RIVKIN RADLER, LLP
Gregory D. Miller
Gene Y. Kang
25 Main Street, Suite 501
Court Plaza North
Hackensack, NJ 07601-7021
Telephone: (201) 287-2460
Facsimile: (201) 4890495
Email: Gregory.miller@rivkin.com

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., AND NORTON (WATERFORD) LTD., PLAINTIFFS, V. CIPLA LTD, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC DEFENDANTS	Consolidated Civil Action No. 2:20-CV-10172-JXN-MAH CONFIDENTIAL

EXPERT REPORT OF GREGOR ANDERSON

TABLE OF CONTENTS

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

I. INTRODUCTION

1. Counsel for Defendants Cipla Ltd. ("Cipla"), Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma, LLC (collectively, "Aurobindo") (all collectively, "Defendants") have retained me to provide technical assistance in this action.

2. I understand that Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, "Teva") allege that Defendants infringe U.S. Patent Nos. 9,463,289 ("the '289 Patent"); 9,808,587 ("the '587 Patent"); and 10,086,156 ("the '156 Patent"); 10,561,808 ("the '808 Patent") (collectively, "the Asserted Patents").[1] In this expert report, I have been asked to provide opinions regarding whether the asserted claims of the Asserted Patents are invalid.

3. I am an independent expert and not a regular employee of any party or counsel to any party in this lawsuit.

II. TOPICS OF OPINIONS

4. In this report, I offer opinions on the following general topics:

- The level of ordinary skill in the art pertaining to the Asserted Patents.
- The general knowledge of the person of ordinary skill in the art ("POSA").
- Whether the Asserted Patents are anticipated.
- Whether the Asserted Patents would have been obvious.
- Whether the Asserted Patents are invalid for lack of written description, lack of enablement, and/or indefiniteness.

[1] I understand that Plaintiffs have agreed to provide covenant not to sue on U.S. Patent No. 10,695,512, and that the parties have agreed that the patent will be dismissed from the litigation. However, as of signing this report, I understand this has not yet occurred. Accordingly, I reserve the right to address the validity of the '512 Patent later, if it is not dropped from the case.

III. QUALIFICATIONS

5. My Curriculum Vitae, which generally sets forth my experience, my qualifications, and my publications for over three decades, is attached as Exhibit A.

6. I received a Master of Science in Polymer Science and Engineering from the University of North London in 1993. I received a Bachelor of Science (CNAA) in Industrial Design and Technology from Napier University in 1985. My undergraduate academic work focused on medical device design and my final year project won the University's Betts Brown Award. My graduate academic focus was initially on surgical and medical devices, then shifted to focus on devices and packing for pharmaceuticals.

7. Since graduating from college, I have worked extensively designing medical devices, including inhalers and dose counters for inhalers. I worked at Glaxo/GlaxoWellcome/GSK from 1989-2017. During my time at Glaxo/GSK, I was the design lead developing a liquid inhaler. I have also designed platforms including: tablet dispensers, nasal devices, smart electronics for pharmaceutical devices, training devices for patients, valved holding chambers, and packaging solutions. I also performed concept engineering for the first metered dose inhaler ("MDI") dose counter to be approved by the FDA (Seretide Evohaler). My work on inhalers has resulted in at least a dozen U.S. and international patents. I also led a team of engineers, analysts, and formulators in the development of a dry powder inhaler, a novel MDI, and MDI enhancements.

8. I was the accountable lead for the development of the novel pack for Ellipta Dry Powder device, which won two design awards in 2015. My experience as a design engineer includes work on the original Imigran Auto-injector, Diskus, GSK's MDI dose counter, and the Ellipta platform.

9. Since leaving GSK in 2017, I have been working as a consultant specializing in device development. I have consulted on design and specialization for novel drug platforms and also the need to integrate sustainable solutions for pharmaceutical delivery systems. I consult on pharmaceutical device and packaging solutions for a wide range of medicinal formulations including inhaled, injectable, and solid dose formats. I also advise on sustainability and connected strategies for these device and packaging platforms. The latter is an area driven by the need for better patient compliance and my experience with counters builds on the opportunities in this area. My clients range from small start-ups to large corporations. I continue to innovate, design and enhance both pharmaceutical devices and packaging using my 30+ years' experience taking concepts through to commercial launch.

10. I have extensive experience as an innovator and inventor, and my inventions have been awarded over 50 United States and International patents, many of which relate to inhalers and dose counters for inhalers.

11. I also have been an invited speaker, presenting technical and business talks at numerous scientific and medical industry meetings and have authored numerous articles published in trade and scientific journals.

12. I am currently on the UK, Institute of Materials (IOM) Board of the Packaging Society, where I represent the Pharmaceutical Industry.

IV. COMPENSATION

13. I am being compensated at my customary hourly rate of £200 per hour for my work on this case. My compensation in no way depends on the substance of my opinions or the outcome of this litigation. I have no financial interest in any of the Parties to this action.

V. PRIOR TESTIMONY

14. In the previous four years, I have not testified as an expert at trial or in deposition.

VI. MATERIALS AND INFORMATION CONSIDERED

15. In forming my opinions, I have considered the materials discussed in this report, including the Asserted Patents, Teva's ProAir Inhalation device with dose counter, Teva's Qvar Inhalation device with dose counter (together, "the Plaintiffs' Devices"), as well as documents and information listed in Exhibit B to this report.

16. Additionally, in forming my opinions, I have relied upon my education, training, and experience in the medical device industry, my personal inspection of the Plaintiffs' Devices, and my evaluation of references available to a POSA at the time the Asserted Patents were filed.

17. The opinions set forth in this report are based on the information of which I am aware to date. I reserve the right to supplement this report should additional information become available, or should Teva present new issues in response to this report.

VII. APPLICABLE LEGAL STANDARDS

18. I am an engineer and product design specialist by training and profession. The opinions I express in this report involve application of my education, training, and technical knowledge and experience to evaluation of the Asserted Patents and the prior art.

19. I am not an expert in patent law. Therefore, I have been advised by Defendants' counsel of certain principles of patent law applicable in this matter, which I have used in arriving at my opinions where appropriate. The paragraphs below express my understanding of these principles, which I applied in forming my opinions.

A. Anticipation

20. I have been informed that a person cannot obtain a patent on an invention if someone else had already made the same invention.

21. I understand that a claim would have been "anticipated," and therefore invalid, if each and every limitation of the claim is found either expressly or inherently in a single prior art

reference. I further understand that if the prior art discloses a single species falling within a claimed genus, the claim is anticipated.

B. Obviousness

22. I have been informed that a person cannot obtain a patent on an invention if the invention would have been obvious to a person having ordinary skill in the art at the time of the invention.

23. I understand that a claim would have been "obvious," and therefore invalid, if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention.

24. I understand that an obviousness analysis involves a number of considerations, including (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the prior art and the claimed invention at the time of the invention, and (4) objective evidence of non-obviousness ("secondary considerations").

25. I understand that the frame of reference when evaluating obviousness is what a hypothetical POSA in the pertinent art would have known as of the earliest priority date of the Asserted Patents. The earliest priority date on the face of the Asserted Patents is May 18, 2010. I understand that the hypothetical POSA is presumed to have knowledge of all pertinent prior art references.

26. I understand that a prior art reference may be a pertinent prior art reference (or "analogous art") if it is in the same field of endeavor as the patent or it is pertinent to the problem the inventors were trying to solve. Here, all of the references I have reviewed in my validity analysis are in the same filed of endeavor as the asserted patents, i.e., inhalation devices. The references are also pertinent to a particular problem the inventors were allegedly focused on, e.g., counting doses.

27. To assess differences between the prior art and the claimed subject matter, it is my understanding that the law requires the claimed invention to be considered as a whole. This "as a whole" assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

28. I understand that the following conditions may indicate that the claimed inventions in the asserted patents would have been obvious:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of known techniques to improve similar devices in the same way;
- Applying a known technique to a known device ready for improvement to yield predictable results;
- "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavor may prompt variations of it for use in either the same filed or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; and
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combined prior art reference teachings to arrive at the claimed invention.

29. I am informed that when considering obviousness of a combination of known elements, the operative question is whether the improvement is more than the predictable use of prior art elements according to their established functions.

30. I am also informed that an obviousness determination must be based on what was known at the time of the invention and that it is improper to focus on just a part or element of the invention, as opposed to the invention as a whole. I understand that when assessing obviousness, using hindsight is impermissible; that is, what is known today or what was learned from the

teachings of the patent should not be considered. The patent should not be used as a road map for selecting and combining items of prior art. Rather, obviousness must be considered from the perspective of a person of ordinary skill in the art at the time the invention was made – May 2010 in this case.

31. I also understand that an obviousness analysis must consider whether there are additional factors that would indicate that the invention would not have been obvious, that is, secondary considerations. These factors include whether there was: (i) a long-felt, unmet need in the industry, (ii) any unexpected results, (iii) skepticism of the invention, (iv) a teaching away from the invention, (v) commercial success, (vi) praise by others for the invention, (vii) copying by other companies, and (viii) failure of others.

32. I understand that in order for a secondary consideration to receive substantial weight, the evidence of secondary considerations must have a nexus to the claims. Put differently, I am informed that the secondary consideration evidence must have a sufficient connection to the patented claims.

C. Written Description

33. I am informed that under 35 U.S.C. § 112, a patent must, as of its priority date, provide an adequate written description of the invention. I understand that in order to satisfy that requirement, the patent specification must describe each and every limitation of a patent claim, in sufficient detail, although the exact words found in the claim need not be used. When determining whether the specification discloses the invention, the claim must be viewed as a whole, rather than as a collection of independent limitations. In the same way, the issue of written description is decided on a claim-by-claim basis, not as to the entire patent or groups of claims.

34. I understand that the written description requirement is satisfied if a POSA in the field of the invention would recognize, from reading the patent specification, that the inventor

possessed the subject matter claimed in the patent. The written description requirement is satisfied if the specification shows that the inventor possessed his or her invention at the time the patent application was originally filed.

35. I am informed that the following factors may be considered in determining whether a specification has provided an adequate written description: (a) the nature and scope of the claim, (b) the complexity predictability, and maturity of the technology at issue; (c) the existing knowledge in the relevant field; and (d) the scope and content of the prior art.

D. Enablement

36. I understand that under 35 U.S.C. § 112, a patent must, as of its priority date, enable a person of ordinary skill in the art to which it pertains to make and use the full scope of the claimed invention without undue experimentation. I further understand that because enablement is judged based on the level of skill in the art existing at the time the inventor filed the patent application, subsequent developments in the art do not necessarily make an otherwise enabling disclosure non-enabling, but post-filing information may be considered that demonstrates the extent of the enabling disclosure. I further understand that not everything necessary to practice the invention need be expressly disclosed, and that what is known may be omitted.

37. I understand that it is the specification, not the knowledge of one skilled in the art, which must supply the novel aspects of an invention in order to constitute adequate enablement. I further understand that the scope of enablement provided to one skilled in the art by the disclosure should be commensurate with the scope of protection sought by the claims. Finally, I understand that, for a claim to be enabled, one skilled in the art must be enabled to make and use the entire scope of the claimed invention without undue experimentation.

38. I understand that the following should be considered when determining if experimentation would be undue:

- The breadth of the claims;
- The nature of the invention;
- The state of the prior art;
- The level of one of ordinary skill in the art;
- The level of predictability in the art;
- The amount of direction provided by the inventor;
- The existence of working examples; and
- The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

39. I am informed that the above factors are known as the "Wands Factors." I understand that not all of the Wands Factors need to be reviewed to find a patent lacks enablement.

E. Indefiniteness

40. I am informed that U.S. patent law requires that the claims of a patent must provide a person of ordinary skill in the art with reasonable certainty as to the objective boundaries of the scope of the claims. I am informed that the definiteness requirement comes from a portion of the U.S. patent statute, 35 U.S.C. § 112, which requires the patent claims to "particularly point[] out and distinctly claim[]" the invention. I am informed the test to be used in assessing whether a claim is indefinite was set forth by the United States Supreme Court, and that the test, which I am to apply, provides that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." I understand that a claim is indefinite where competitors trying to practice the invention or to design around it would be unable to discern the bounds of the invention. I further understand that simply because some claim language may not be precise, that does not necessarily render a claim invalid. I understand that

indefiniteness is to be evaluated from the perspective of someone skilled in the relevant art as of the priority date.

41. I reserve the right to change or formulate new opinions if there is a material change in the law concerning patent validity between now and trial.

VIII. CLAIM CONSTRUCTION

42. I understand that during the course of this action the Parties could not reach agreement on the construction of a number of disputed claim terms. I also understand that the Court has considered the Parties' positions on the construction of those terms, but has not yet ruled as of the date of my report. Where the Parties' proposed constructions differ, I have offered opinions under both constructions. Should the Court adopt a construction different from the constructions offered by the Parties, I reserve the right to supplement my report to address validity under the Court's adopted construction(s).

Term	Defendants' Construction	Teva's Construction
"actuation member"	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"	"a component of the dose counter's actuator that transmits motion from the canister to the actuator"
"[lying or lie] in a common plane coincident with the longitudinal axis X"	"aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member"	Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting these features that passes through the center of the stem block.
"positioned at opposite ends of the inside surface of the main body to face each other"	"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"	"located on opposite sides from on each other on the inside surface of the main body, and extending outwardly from the inner wall towards each other"

"step[s] formed thereon"	"a stepwise increase in the extent to which the support rail extends inwardly"	"a location of changing width dimension thereon"
"canister fire sequence"	"process of ejecting medicament from an inhaler where the actuator pawl follows a sequence of movement from the start configuration to the rest configuration to the fire configuration, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel"	"sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"
"first reset position"	"configuration in which the actuator pawl is above the datum plane, but close to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"	"a position of the actuator in which the actuator is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration"
"canister fire sequence"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"	"a configuration of the dose counter whereby the dosage indicator has indicated a count"
"count configuration"	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"	"configuration of the dose counter whereby the dosage counter has indicated a count"
"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"	"plane passing though the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve	"a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction

	stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"	of movement of the medicament canister"
"the body" ('156 Patent claim 12)	Indefinite	"dose counter body"
"first station"	"first structure on which the counter display is located"	"a first region"
"second station"	"second structure, separate from the first structure, to which the counter display is moved"	"a second region"
"aperture"	"hole"	"an opening or open space: hole"
"separate counter chamber"	"discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"	"a separate chamber of the inhaler in which the dose counter is located"
"count pawl"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"	"a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the ratchet wheel"

43. I understand that the Parties entered into a Joint Stipulation in which other disputed claims terms were agreed to have the following meanings:

Term	Agreed-Upon Construction
"canister housing"	"the portion of the inhaler body that is arranged to retain a medicament canister"
"inside surface"	"an interior surface"
"body"	"the body of the inhaler"
"associated with"	"related to"
"canister support formation"	"a formation arranged to reduce canister rocking"
"actuator"	"A structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at

	least one additional dose counter component."
"actuator pawl arranged to engage with a first tooth of the ratchet wheel"	"a structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component"
"actuator pawl arranged to engage with a first tooth of the ratchet wheel"	"a pawl that is part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel"
"wall surfaces separating the canister receiving portion and the counter chamber"	"wall surfaces of the inhaler body which are substantially perpendicular to the direction of canister movement and which divide the canister-receiving portion and counter chamber"
"regulate motion of the counter display"	"modulate motion of the counter display"
"ratchet wheel"	"wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl"
"first direction"	"single direction at a time"
"main surface of the inner wall"	"inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of movement of the medicament canister when it is pressed downward by the user to expel medicament"
"inner wall through which a portion of the actuation member extends"	"an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament"
"inner wall"	"an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body"
"protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler"	"guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose

	counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter"

44. In reaching my opinions on all of the asserted claims, I have applied the Parties' proposed constructions or the Parties' agreed constructions, or the plain and ordinary meaning of the term. I have also indicated where the Parties' differing constructions has impacted my opinion. Unless otherwise stated, my invalidity opinion is the same regardless of which proposed construction is applied. In my opinion, the plain and ordinary meaning that I have applied in each instance is consistent with how the term would be understood by one of ordinary skill in the art at the time of the invention in light of the specifications of the Asserted Patents.

IX. ASSERTED CLAIMS

45. I understand that the following patent claims are being asserted in this case against the Defendants ("Asserted Claims"):

Patent	Asserted Claims
'289 Patent	1-8
'587 Patent	1-8, 11-22
'156 Patent	1-2, 9, 11-13
'808 Patent	1, 27-28

46. Should this list change, I reserve the right to provide my opinions on any other claims that are asserted.

X. BACKGROUND OF THE RELEVANT TECHNOLOGY

47. Inhalation devices have been used to treat lung complaints for thousands of years. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/. As early as 1778 inhalation devices

were used to treat coughs. https://www.immunology.org/inhaler-1956#:~:text=English%20doctor%20John%20Mudge%20invented,form%20of%20a%20liquid%20spray. The first modern-day inhaler for the treatment of asthma was developed in 1956. *Id.* Today, the metered dose inhaler (MDI) is the gold standard for delivery of medication to the lungs and is the most commonly used device in the treatment of asthma. *Id.*; *see also e.g.,* '406 Publication at [0002]; '552 Publication at 1:3-13; '191 Publication at [0003]; '712 Publication at 1:6-10; '514 Publication at 1; '627 Patent at Abstract; '822 Patent at Abstract; '066 Patent at Abstract; '139 Publication at [0001]; GB '489 at 1:1-7; '558 Publication at [0001]; '755 Patent at Abstract; '159 Publication at Abstract.

48. MDIs generally share a number of common structural traits. Modern MDIs are typically comprised of an aerosol canister, containing medication formulated with a propellant, and an actuator with a mouthpiece, typically a plastic housing that receives the canister. *See, e.g.,* '406 Publication at [0003]; '552 Publication at 1:15-18;'191 Publication at [0004]-[0005]; '008 Publication at [0013]; '712 Publication at 1:11-16; '965 Publication at 5:8-21; '817 Publication at [0013]; '044 Publication at Abstract; '514 Publication at 1:3-9; '822 Patent at Abstract; '066 Patent at 2:11-14; '139 Publication at [0001]-[0002]; '558 Publication at [0002]; '159 Publication at [0007].

49. The canister generally includes a valve with a valve stem that compresses, allowing medication to be discharged. *See, e.g.,* '406 Publication at [0003]; '552 Publication at 1:20-24; '191 Publication at [0004]-[0005]; '712 Publication at 1:16-19; '514 Publication at 1:14-17; '627 Patent at 1:35-38; '822 Patent at 3:19-25; '066 Publication at 2:24-31; '139 Publication at [0002]; GB '489 at 1; '558 Publication at [0002]; '159 Publication at [0012]-[0016]. The MDI actuator typically includes a location or structure adapted to receive the valve stem ("valve stem block").

See, e.g., '406 Publication at [0003]; '552 Publication at 1:20-24; '021 Publication at [0005]; '712 Publication at 1:22-24; '514 Publication at 1:19-22; '627 Patent at 1:24-26; '822 Patent at 3:14-17; '066 Publication at 2:24-31 and 2:43-48; '139 Publication at [0002]; '159 Publication at [0012]-[0016]. Generally, movement of the valve stem into the discharge position is caused by pushing down on the canister, causing the valve stem to compress in the valve block. *See, e.g.,* '406 Publication at [0003]; '552 Publication at 2:1-6; '008 Publication at [0026]; '712 Publication at 2:1-3; '965 Publication at 5:27-31; '514 Publication at 1:22-24; '627 Patent at 1:28-41; '822 Patent at 3:19-25; '139 Publication at [0002]; '558 Publication at [0002]. When the valve stem moves a defined distance to the discharge position, a dose of medication is dispensed. *See, e.g.,* '406 Publication at [0003]; '552 Publication at 2:1-6; '008 Publication at [0045]; '712 Publication at 1:24-28; '965 Publication at 5:32- 6:7; '514 Publication at 1:22-24; '627 Patent at 1:28-41; '822 Patent at 3:19-27; '139 Publication at [0002]; '558 Publication at [0002]. An illustration of an exemplary MDI actuator with a canister in the rest and discharge positions is shown below:

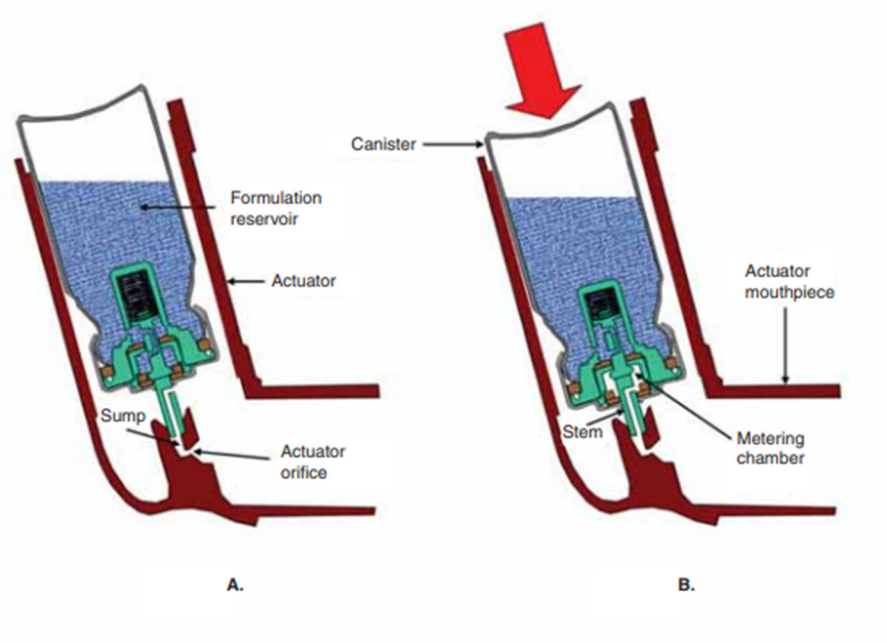


Figure 1. Illustration showing MDI's dose discharge route. A. MDI in rest position – metering chamber open to formulation reservoir. **B.** MDI in actuation position following dose discharge from metering chamber – metering chamber open to atmosphere.
MDI: Metered-dose inhaler.

Lewis at 236.

50. Another feature that has been common in MDI inhalers for decades is a series of "ribs" within the canister receiving portion of the actuator. Historically, the actuator's housing extended only to the top of the valve (as shown below in the Medihaler-ISO – the first FDA approved MDI in 1956).

51. In 1965, the standard actuator was redesigned to extend to encompass and support the canister. *See* Lewis at 236. This redesign "introduced four equally spaced ribs to locate the container, and provide an annular passageway to draw air using the mouthpiece." *Id*. In addition, the "support provided by the modified actuator [and ribs] was introduced to prevent accidental opening of the valve as a result of unintentional axial movement of the valve stem. The updated design remains an important feature of present actuators." *Id*.; *see also* '755 Patent at 1:80-83, 2:45-56, Fig. 4; '159 Publication at Fig. 3; '949 Publication at Fig. 6 and [0076]-[0077]; '008 Publication at Fig. 7 and [0045] (referring to ribs provided to hold the external surface of the container); '514 Publication at Fig. 2a; '822 Publication at 3:10-14; '066 Patent at 2:31-34; '139 Publication at [0045]; '558 Publication at [0066].

52. Another feature shared by nearly all modern MDIs is the inclusion of a dose counter or dose indicator. In 2004, GSK launched the Seretide Evohaler—the first MDI with an integrated dose counter. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/. In addition, in 2003, the FDA issued a Guidance for Industry requiring all new MDI products in the U.S. to have dose counters or dose indicators. *Id*. Since then, most MDIs have included integrated dose counters. *See, e.g.,* '552 Publication; '406 Publication; '191 Publication; '949 Publication; '008 Publication; '712 Publication; '965 Publication, '817 Publication; '044 Publication; '021 Publication, '518 Publication, '102 Publication, '950 Publication; '514 Publication; '822 Publication; '066 Patent; '139 Publication; GB '489 Publication; '558 Publication; '755 Patent.

53. Mechanically, dose counters may come in a variety of forms. However, two types which are relevant to my opinions are tape-based dose counters and gear-based dose counters. In gear-based dose counters, actuation of the inhaler results in the rotation of one or more plastic rings, such as the tens cone and unit display ring in the exemplary gear-based dose counter

disclosed in the ’406 Publication, shown below (Fig. 21). *See also, e.g.,* ’514 Publication at Fig. 5-6; ’822 Patent at Figs. 1-6; ’066 Patent at Fig. 2; ’139 Publication at Figs. 5-6; ’558 Publication at Figs. 5-6. Each plastic ring has a form of indicia, such as numbers, located on the surface of the rings. The indicia are visible through a display located on the body of the inhaler. Another exemplary gear-based dose counter is disclosed in the ’712 Publication, also shown below (Fig. 7).

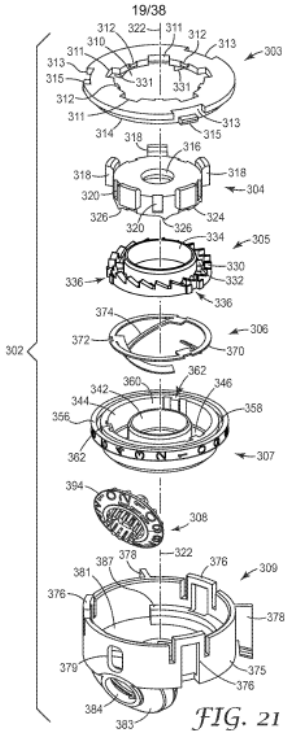


FIG. 21

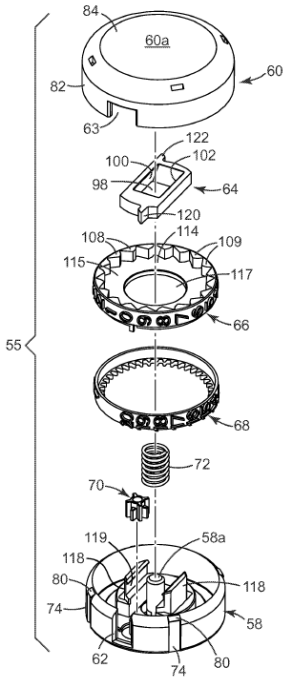
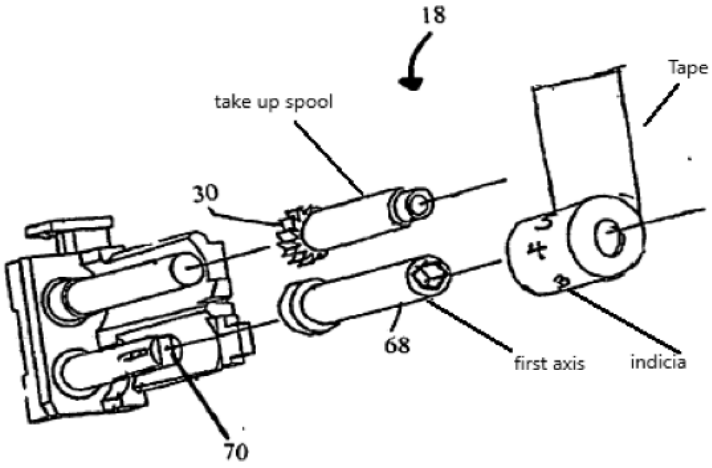


FIG. 7

54. In tape-based dose counters, the count is displayed on a tape, which is typically wrapped around a first axis, then, as the inhaler is actuated, a second axis rotates, drawing the tape display to the second axis (or take up spool). *See, e.g.,* ’552 Publication at 4:19-31, ’627 Patent at Figs. 2 and 3; ’552 Publication at 4; GB ’489 at Figs. 2-3; ’950 Publication at Fig. 14. The surface of the tape is covered with a form of indicia, such as numbers, which provides information about the number of doses remaining in the inhaler, and is visible through a display located on the body of the inhaler when the tape is drawn from the first axis to the take up spool. *See, e.g.,* ’552

Publication at 4:19-31; *see also, e.g.*, '950 Publication at Fig. 14, '627 Patent at Fig. 3. An exemplary tape system is shown below:



55. Tape-based counters were known to have certain draw-backs. For instance, if dropped the tape could easily unravel. In addition, many of the tape-based systems record a count when a pin is depressed by the canister. *See e.g.*, '552 Publication, '627 Patent, '950 Publication. This method of actuation is susceptible to miscounts during transportation if the canister moves on its axis in the direction of the pin.

XI. LEVEL OF ORDINARY SKILL IN THE ART

56. I understand that in determining the level of ordinary skill in the art, several factors are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and (v) the educational level of active workers in the field. I understand that these factors are not exhaustive but are merely a guide in determining the level of ordinary skill in the art. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

57. I understand that the level of ordinary skill in the art should be determined as of the earliest priority date of the Asserted Patents. The Asserted Patents assert priority back to U.S.

Provisional Patent Application Serial No. 61/345,763, which was filed on May 18, 2010. Therefore, according to the face of the Patents-in-Suit, the earliest possible priority date is May 18, 2010, and the earliest possible critical date under 35 U.S.C. § 102(b) is May 18, 2009.[2]

58. A person of ordinary skill in the art pertaining to the subject matter of Patents-in-Suit, as of the earliest possible effective U.S. filing date of May 18, 2010, would have been a person with a bachelor's degree in pharmaceutical science or a related discipline, and at least 2-3 years of product development experience with design and manufacture of metered dose inhalers. Alternatively, a person of ordinary skill in the art would have a master's degree or Ph.D. in pharmaceutical science, mechanical or medical device engineering, or a related discipline, and at least 1-2 years of product development experience with metered dose inhalers and counter systems. A POSA may have also worked as part of a multi-disciplinary team of scientists in pursuit of developing a pharmaceutical product and drawn upon not only his or her own skills, but also consulted with others of the team having specialized skills.

59. I understand that Plaintiffs have, thus far, failed to provide any alternative definition of a person of ordinary skill in the art. Therefore, I presume the accuracy of the above description. I reserve the right to address any proposed definition Plaintiffs belatedly offer, should they be allowed to do so.

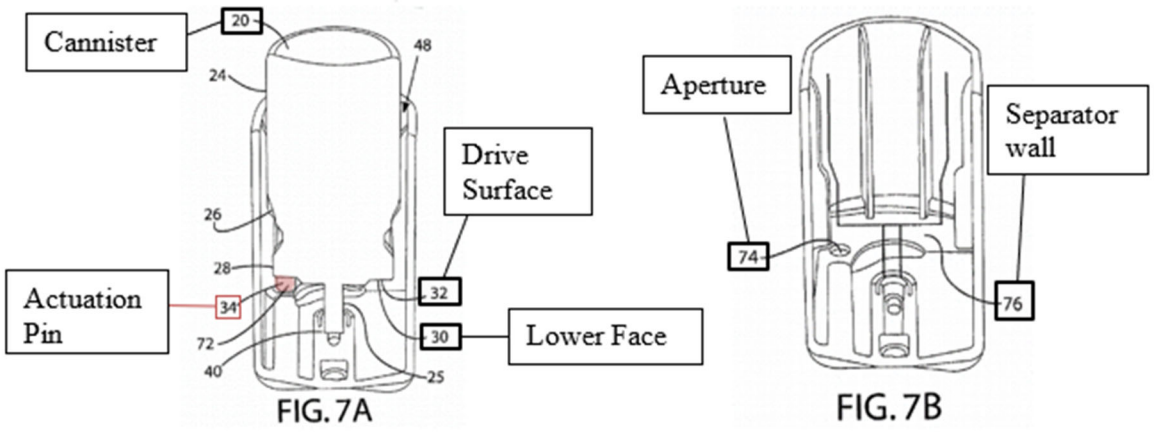
XII. SUMMARY OF THE ASSERTED PATENTS

60. Plaintiffs are asserting five patents against Defendants, all of which share a common specification and are related. Accordingly, throughout this report citations to this shared specification will generally be to the '289 Patent. Each of the Asserted Patents relates specifically

[2] Because the Asserted Patents claim priority to filing dates that pre-date the America Invents Act (AIA), I refer to the pre-AIA statute.

to the dose counter of an inhaler, alone or in combination with an actuator. *See generally*, '289 Patent, '587 Patent, '156 Patent, and '808 Patent.

61. In general, the Asserted Patents describe an inhaler where, in use, a canister is placed into the main body of an actuator. '289 Patent at 12:16-19. The canister is generally cylindrical and includes a lower face 30, which has an outer annular drive surface 32 that engages upon and drives an actuation pin 34 (colored light red) of the dose counter 36. *Id.* at 12:19-23. The actuation pin protrudes through an aperture 74 of the separator wall 76 of the main body 10 of the inhaler. *Id.* at 12:46-53. These features are depicted in Figures 7A and 7B, below:



62. The actuation pin 34 is biased upwardly by a spring. *Id.* at 12:39-41. The actuator pin is connected to an actuator pawl 80. *Id.* at 12:54-55. The actuator pawl is connected to the drive teeth 92 of the ratchet wheel 94 of the drive system of the dose counter. *Id.* at 12:55-13:2. These features are shown, for example, in Figure 6H, below:

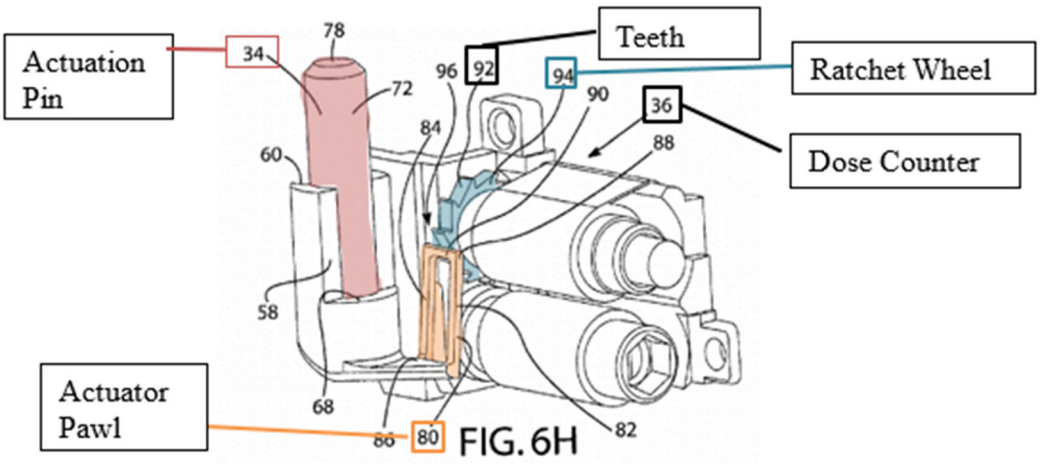


FIG. 6H

When the user sufficiently presses down on the canister, it depresses the actuator pin 34 (light red), causing the actuator pawl (orange) to rotate the drive teeth 92 (teal) of the ratchet wheel 94 (teal), and thereby causing the dose counter to count one dose (as described in more mechanical detail below). *See id.* at 14:40-15:32.

63. The dose counter of the Asserted Patents contains a number of components, including a set of two shafts (first 104 and second shaft 108). A tape reel shaft 106 (green) is placed on the first shaft 104. A tape stock bobbin 110 (purple)is placed on the second shaft 108. '289 Patent at 13:3-9. A tape 112 (beige), containing numbers 114 is initially placed on the tape stock bobbin 110 and incrementally wound onto the tape reel shaft 106 during use. *Id.* at 13:10-22. These features are shown in Figures 6A and 6B, below:

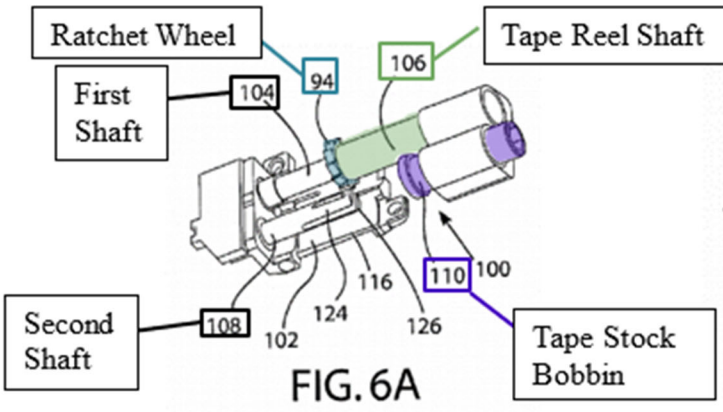


FIG. 6A

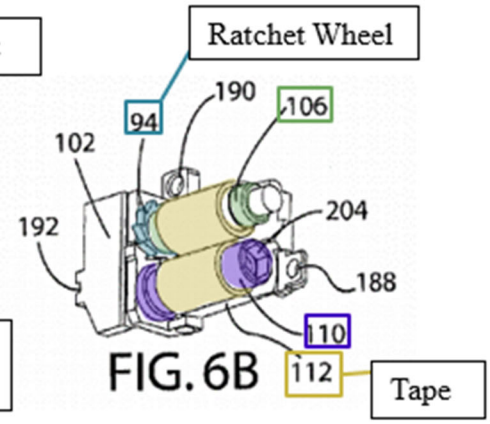


FIG. 6B

64. As previously discussed, when the actuation pin 34 is depressed, thereby moving the actuator pawl, which rotates the ratchet wheel 94 (teal), it causes an incremental rotation of the tape reel shaft 106 (green), thereby causing the tape 112 (beige) to advance one increment from the tape stock bobbin 110 (purple) to the tape reel shaft 106 (green). *See id.* at 14:40-15:32.

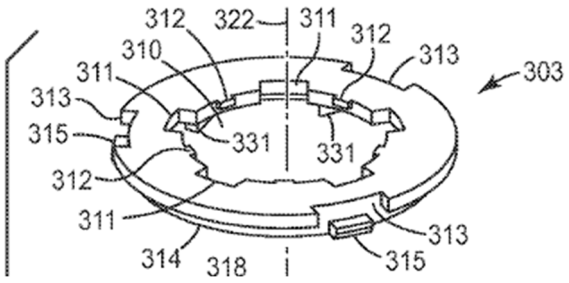
65. Additional features of the Asserted Patents that relate to the independent claims of each patent are discussed below as related to the invalidity of each of the Asserted Patents.

XIII. SUMMARY OF THE ACCUSED PRODUCTS[3]

66. The Defendants' ANDA Products utilize a completely different method and device for counting doses compared to that of the claims of the Asserted Patents. Rather than using a tape based system, as described in the Asserted Patents, the Defendants use a gear based system that was disclosed in 2007 in WO 2007/124406 ("the '406 Publication").

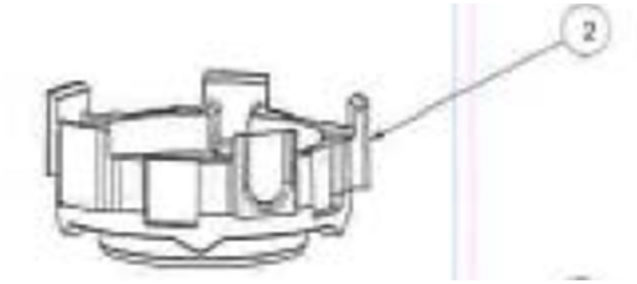
67. The dose counter used by Defendants includes a lid, indexer, teeth ring, leaf spring, units display ring, tens cone, and housing. *See, e.g.,* CIPLA-BDI_0156579; AURO_BECL00005977. The '406 Publication discloses a dose counter comprised of a lid, indexer, teeth ring, leaf spring, units display ring, tens cone, and housing. '406 Publication at [00135], [00149], Fig. 21. A side-by-side comparison of these parts is shown below:

Lid

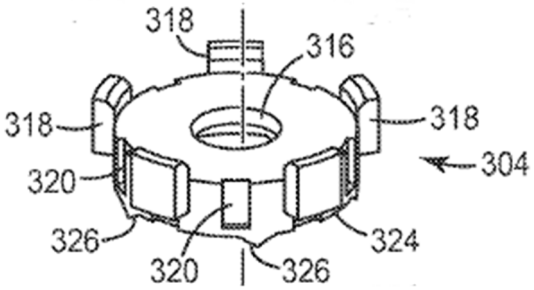


Lid

[3] Although I cite to the Cipla ANDA Product throughout this report, I understand the actuators and dose counters of both Defendants' ANDA Products to be materially the same.

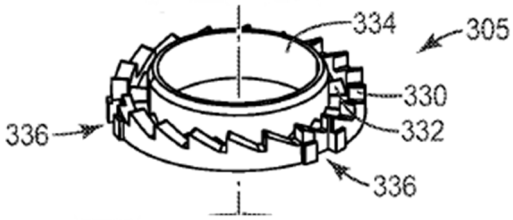


Indexer



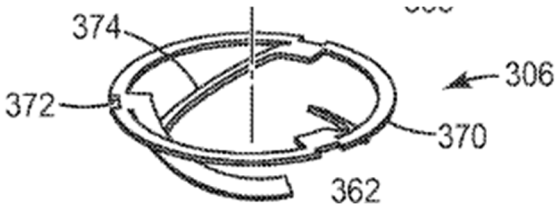
Indexer

Units Teeth Ring



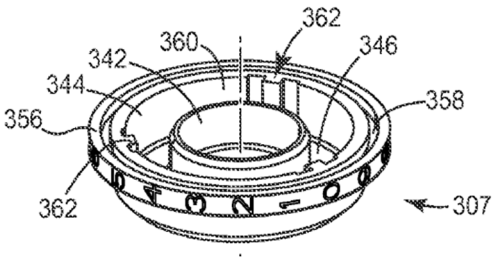
Units Teeth Ring

Leaf Spring

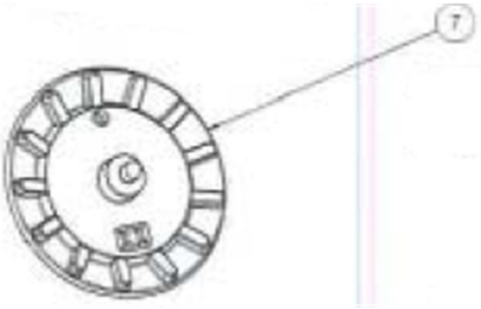


Leaf Spring

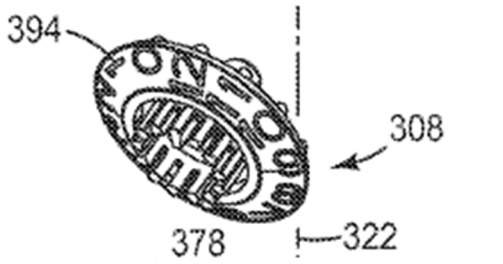
Units Display Ring



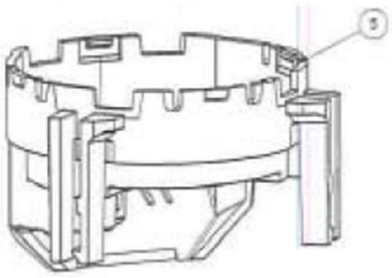
Units Display Ring



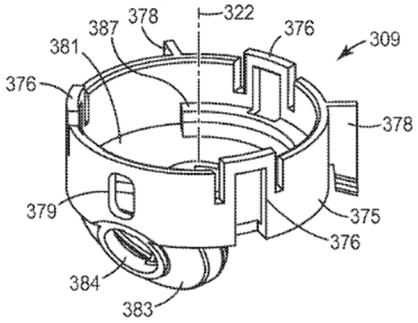
Tens Cone



Tens Cone



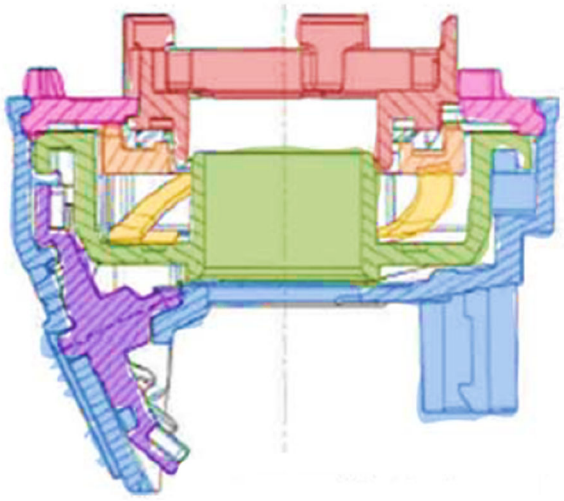
Housing



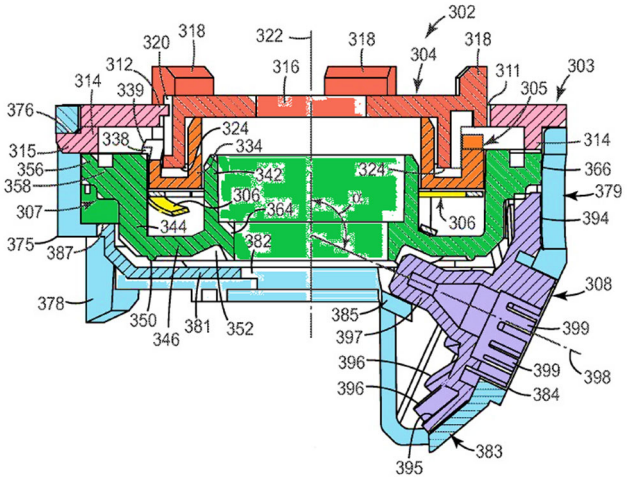
Housing

See CIPLA-BDI_0156579; AURO_BECL00005977; '406 Publication, Fig. 21

68. An assembled view of each dose counter, with the parts color-coded is below. The housing is shown in blue, the tens cone in purple, the units teeth ring in green, the leaf spring in yellow, the teeth ring in orange, the indexer in red, and the lid in pink. Assembled, the two dose counters are essentially identical.



Defendants' Dose Counter



'406 Publication, Fig. 26

69. The '406 Publication describes a dose counter, where the compression spring 306 biases the units teeth ring 305 upward, so that the outer ring of teeth 330 on the top of the units teeth ring 305 is in engagement with ratchet members 326 on the bottom of the lid 303, and the castellations 22 of the indexer 4 extend upward through the slots 14 in the lid 3. *See, e.g., id.* at [00150], *see also, e.g.,* [00092]–[00102], [00106], and [00114]. Pressing the canister 70 downward along the central axis 13 causes the bottom of the canister 70 to push the castellations 318 of the indexer 4 downward and forces the indexer 304 and the units teeth ring 305 in a downward direction, pressing the sawtooth projections 326 on the bottom of the indexer 304 into engagement with the inner teeth 332 on the top of the units teeth ring 305. *See id.*

70. The contact angle between the sawtooth projections 326 on the bottom of the indexer 304 and inclined surfaces of the corresponding inner teeth 332 of the units teeth ring 305 exerts a rotational force in a first direction on the units teeth ring 305, but the units teeth ring 305 is prevented from rotating in the first direction by the continued engagement of the ratchet

members 331 with the outer ring of teeth 330 of the units teeth ring 305. *See, e.g.,* '406 Publication at [00150]; *see also, e.g.,* [00092]–[00102], [00106], & [00114] (citing PCT Application WO 2005/060535).

71. Once the units teeth ring 305 is depressed to the point that the outer ring of teeth 330 of the units teeth ring 305 disengage the ratchet members 331 on the bottom of the lid 303, the units teeth ring 305 rotates in the first direction under the rotational force, moving adjacent outer teeth 330 into alignment with the ratchet members 331 on the bottom of the lid 303. *See, e.g., id*. The compression spring 306 returns the units teeth ring 305 upward back into engagement with the ratchet members 331 on the bottom of the lid 3, the contact angle of which exerts additional rotational force on the units teeth ring 305. *See, e.g., id*. The units teeth ring 305 rotates in the first direction until the ratchet members 331 on the bottom of the lid 303 and outer ring of teeth 330 of the units teeth ring 305 come into full engagement, preventing further rotation. *See e.g., id*. The rotation of the units teeth ring 305 corresponds to the actuation and dispensing of a single dosage of medication. *See, e.g., id*. The units rotational ring 307, bearing ones units indicia on its outer circumference 344, is rotationally fixed to the units teeth ring 305 so that the units rotational ring 307 rotates with the units teeth ring 305. *See, e.g., id*. Every tenth actuation is further configured to rotate the tens cone 308, seated in the housing 309 of the dose counter 302. *See, e.g., id*.

72. In addition, assembled in an actuator, the '406 Publication and the Defendant's ANDA Products remain similar. A side-by-side comparison of the images below shows that they have similar design elements, including a "datum plane line that passes through a shoulder of a valve stem block configured to receive the medicament canister" (red line) located below the housing of the dose counter (purple line).

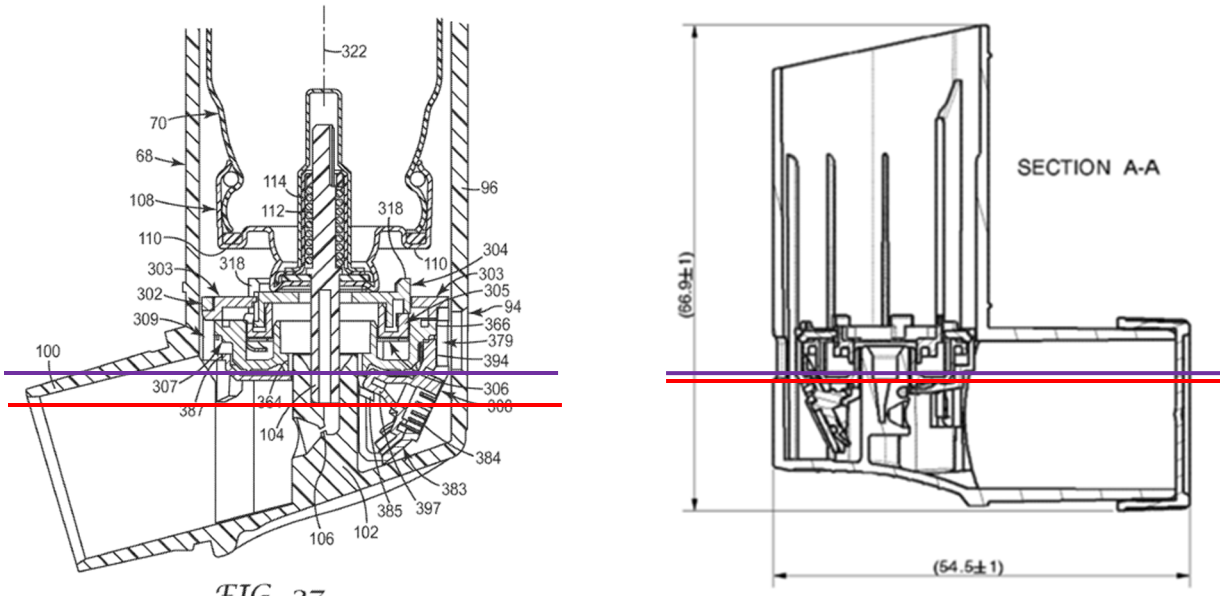


FIG. 27

73. I have inspected a sample of Cipla's dose counter and confirmed that Cipla's dose counter works in the exact same manner as that disclosed in the '406 Publication. In my opinion, any slight differences between the disclosure of the '406 Publication (for example the shape of leaf spring and the shape of the housing legs) and the Defendants' dose counter is irrelevant to the function of the dose counter.

XIV. PRIOR ART

A. Identification of Prior Art

(i) *The '406 Publication*

74. International Patent Publication No. WO 2007/124406 ("the '406 Publication") published on November 1, 2007. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '406 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '406 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(ii) *The '552 Publication*

75. International Patent Publication No. WO 2008/119552 ("the '552 Publication") published on October 9, 2008. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '552 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '552 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(iii) *The '514 Publication*

76. International Patent Publication No. WO 2003/101514 ("the '514 Publication") published on December 11, 2003. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '514 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '514 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(iv) *The '021 Publication*

77. United States Patent Publication No. 2002/0047021 "(the '021 Publication") published on April 25, 2002. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '021 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '021 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(v) *The '998 Publication*

78. U.S. Design Patent No. D416,998 ("the '998 Patent") issued on November 23, 1999. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '998 Patent published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '998 Patent is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(vi) *The '950 Publication*

79. U.S. Patent Publication No. 2002/0078950 ("the '950 Publication") published on June 27, 2002. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '950 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '950 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(vii) *The '008 Publication*

80. U.S. Patent Publication No. 2006/0289008 ("the '008 Publication") published on December 28, 2006. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '008 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '008 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(viii) *The '822 Patent*

81. U.S. Patent No. 4,817,822 ("the '822 Patent") issued on April 4, 1989. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '822 Patent published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '822 Patent is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(ix) *The '066 Patent*

82. U.S. Patent No. 7,407,066 ("the '066 Patent") issued on August 5, 2008. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '066 Patent published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '066 Patent is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(x) *The '627 Patent*

83. U.S. Patent No. 6,446,627 ("the '627 Patent") issued on Sept. 10, 2002. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '627 Patent published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '627 Patent is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xi) *The '668 Patent*

84. U.S. Patent No. 8,584,668 ("the '668 Patent") was filed February 3, 2006, published September 28, 2006 and issued November 19, 2013. Thus, the '668 Patent published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '668 Patent is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b). Alternatively, to the extent Plaintiffs contend that the disclosure of the '668 Patent somehow differs from the disclosures in its publication, I understand that the '668 Patent is still prior art under 35 U.S.C. §102(e).

(xii) *The '260 Publication*

85. International Patent Publication No. WO 2004/060260 ("the '260 Publication") issued on July 22, 2004. The Asserted Patents have an earliest claimed priority date of May 18, 2010. Thus, the '260 Patent published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '260 Patent is, therefore, prior art to the Asserted Patents under 35 U.S.C. § 102(b).

(xiii) *The '191 Publication*

86. U.S. Patent Application Publication No. US 2005/0087191 ("the '191 Publication") published on April 28, 2005. Thus, the '191 Publication published more than one year prior to the

earliest claimed priority date of the Asserted Patents. I understand that the '191 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xiv) *The '712 Publication*

87. International Patent Publication No. WO 2007/103712 ("the '712 Publication") published on September 13, 2007. Thus, the '712 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '712 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xv) *The '139 Publication*

88. European Patent Publication No. EP 1,369,139 ("the '139 Publication") published December 20, 1996. Thus, the '139 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '139 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xvi) *GB '489*

89. United Kingdom Patent Publication No. GB 2,320,489 ("GB '489") published June 24, 1996. Thus, GB '489 published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that GB '489 is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xvii) *The '558 Publication*

90. U.S. Patent Application No. US 2005/0209558 ("the '558 Publication") published September 22, 2005. Thus, the '558 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '558 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xviii) *The '755 Patent*

91. United Kingdom Patent No. GB 994,755 ("the '755 Patent") published on June 10, 1965. Thus, the '755 Patent published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '755 Patent is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xix) *The '159 Publication*

92. European Patent Publication No. EP 1,321,159 ("the '159 Publication") published on June 25, 2003. Thus, the '159 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '159 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xx) *The '965 Publication*

93. International Patent Publication No. WO 2006/126965 ("the '965 Publication") published on November 30, 2006. Thus, the '965 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '965 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xxi) *The '817 Publication*

94. United States Patent Application Publication No. US 2007/0277817 ("the '817 Publication") published on December 6, 2007. Thus, the '817 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '817 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xxii) *The '044 Publication*

95. International Patent Publication No. WO 2005/113044 ("the '044 Publication") published on December 1, 2005. Thus, the '044 Publication published more than one year prior

to the earliest claimed priority date of the Asserted Patents. I understand that the '044 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xxiii) *Lewis*

96. *Metered-Dose Inhalers: Actuators Old and New* published in Expert Opin. Drug Deliv. in 2007 ("Lewis"). Expert Opn. Drug. Deliv 4(3):235-245. Thus, Lewis published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that Lewis is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xxiv) *The '949 Publication*

97. U.S. Patent Application Publication No. US 2006/0107949 ("the '949 Publication") published on September 13, 2007. Thus, the '949 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '949 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xxv) *The '518 Publication*

98. U.S. Patent Application Publication No. US 2007/0062518 ("the '518 Publication") published on March 22, 2007. Thus, the '518 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '518 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

(xxvi) *The '102 Publication*

99. United States Patent Publication No. US 2007/0210102 ("the '102 Publication") published on September 13, 2007. Thus, the '102 Publication published more than one year prior to the earliest claimed priority date of the Asserted Patents. I understand that the '102 Publication is, therefore, prior art to the Asserted Patents under 35 U.S.C. §102(b).

B. Summary of Motivations to Combine Prior Art References

100. The prior art references that I rely on herein are within the same field of the patentee's endeavor (inhalers and dose counter for use in inhalers). In my opinion, each of the Asserted Claims simply arranges elements ubiquitous in the prior art, with each performing the same function it had been known to perform at the time of the invention, and the combination yields no more than what a person of skill in the art would expect from such an arrangement.

101. In addition, the alleged "inventions," were merely responses to well-recognized design needs and market pressures. For example, since 2003, the FDA had been requiring that MDI inhalers include dose counters or indicators that informed patients when their inhalers were running low with "as close to 100 percent reliab[ility] as possible" *See* 2003, FDA Guidance for Industry, Integrations of Dose-Counting Mechanisms into MDI Drug Products, US Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Clinical Medical, March 2003 at 3 ("2003 FDA Guidance"). These market pressures would provide a person of skill in the art motivation to combine prior art elements to improve on existing dose counters to improve accuracy and reliability.

102. In addition, there are a finite number of predictable solutions to problems known in dose counters. For example, if a dose counter sits loosely in an inhaler, it could be removed and tampered with, and the loose fit may cause inaccuracies in counting. A finite number of simple solutions, such as tightening a snap-fit connection or welding/heat staking the counter to the body are the two most obvious choices as, in 2009 and even earlier, both were commonly used for connecting inhaler parts.

103. For at least these reasons, a person of skill in the art would have been motivated to combine prior art references, and would have had a reasonable expectation of success in doing so.

104. In addition to these general motivations, which would apply to all of my obviousness combinations in this report, I provide additional specific motivations for particular combinations in my opinions below.

XV. INVALIDITY OF THE COMMON PLANE PATENTS

105. The '289 Patent and '587 Patent (together the "Common Plane Patents") each recite limitations related to certain structures being aligned in the same plane. Each independent claim of the '289 and '587 Patents include a "Common Plane Limitation" requiring that an "inner all canister support formation," the "actuation member," and the "central outlet port" all lie in "a common plane, coincident with longitudinal axis X." '289 Patent at 22:9-12, '587 Patent at 21:50-52, 22:42-44. During prosecution of the '289 Patent, the Applicants illustrated the Common Plane Limitation, explaining that Figure 7D (reproduced below) depicts the "inner wall canister support formation 144, the actuation member at 74, and the central outlet port 148 [lying] in a common plane with longitudinal axis X at 148." '289 Patent Prosecution History, March 7, 2016 Office Action Response at 5.

106. In addition, the '289 and '587 Patents are directed to an inhaler with an actuator (or body) that includes a canister support formation that "can prevent a canister from rocking too much relative to the main body of the inhaler. Since the canister may operate the actuation member of the dose counter, this substantially improves dose counting and avoids counter errors." '289 Patent at 6:44-49.

107. During prosecution, the Applicants explained that the particularly claimed arrangement of the actuation member, the central outlet port, and the inner wall canister support formation "has the advantage of preventing the canister from rocking towards the position of the dose counter actuation member, which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter." '289 Patent Prosecution History,

March 7, 2016 Office Action Response at 5. In allowing the claims, the Examiner explained, "The examiner is persuaded that rocking by the canister about its central axis in the direction of the actuation member could risk triggering false counting, and that a canister support formation directly in line with the actuation member and the central canister axis could prevent rocking in this direction and thus reduce false counts." '289 Patent Prosecution History, May 20, 2016 Notice of Allowance at 2-3.

108. I understand that Plaintiffs are asserting claims 1-8 from the '289 Patent and claims 1-8 and 11-22 from the '587 Patent.

109. As discussed in detail below, in my opinion, each asserted claim of the Common Plane Patents is invalid in view of the prior art.

A. The Asserted Claims of the Common Plane Patents are Anticipated by the '406 Publication

(i) *Claims 1-3 of the '289 Patent are Anticipated by the '406 Publication*

110. In my opinion, claims 1-3 of the '289 Patent are invalid at least because they are anticipated under 35 U.S.C § 102(b) by the '406 Publication.

111. Claim 1 is the only independent claim of the '289 Patent. Claims 2-3 depend, either directly or indirectly, from Claim 1. Claim 1 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the

> actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

'289 Patent, claim 1. Each limitation of Claim 1 is disclosed by the '406 Publication.

112. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** To the extent the preamble is limiting, the '406 Publication discloses an inhaler for metered dose inhalation. *See, e.g.,* '406 Publication at Fig. 27, [0067] and [00149].

113. ***Limitation 1A: "a main body having a canister housing."*** The '406 Publication discloses an inhaler comprising a main body with a canister housing. *See, e.g.,* '406 Publication at [00149] actuator housing 68.

114. ***Limitation 1B: "a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and."*** The '406 Publication discloses a medicament canister (aerosol container 70), which is moveable relative to the canister housing. *See, e.g.,* '406 Publication at [00106]. The medicament canister (aerosol container 70) in the '406 Publication is retained in a central outlet port of the canister housing, such that the canister fire stem of the medicament canister (aerosol container 70) mates with the outlet port. *See, e.g., id.* at Fig. 27, ¶¶ [0003], [00104], [00149] and [00150] ("nozzle block 102 . . . has an aperture to accommodate a valve stem 104 of the aerosol container 70").

115. ***Limitation 1C: "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** The '406 Publication discloses incorporating a dose counter into the inhaler for metered dose inhalation. *See, e.g., id.* at Fig. 27 (showing a "press-and-breathe" inhaler incorporating the dose counter of Figs. 21, 24, 25, and 26). The '406 Publication further discloses dose counters having indexer 304 with castellations (318) which are at least partially located in the canister

housing. *See, e.g.,* Fig. 27 (reproduced below). When the inhaler disclosed in the '406 Publication is actuated, "downward movement of the aerosol container 70 causes the valve ferrule 110 to push down on the indexer 304." *See, e.g., id.* at [00149-00150], Fig. 27 (castellations 318 circled in blue, valve ferrule circled in purple); *also, e.g., id.* at [0003], [0004], [00104].

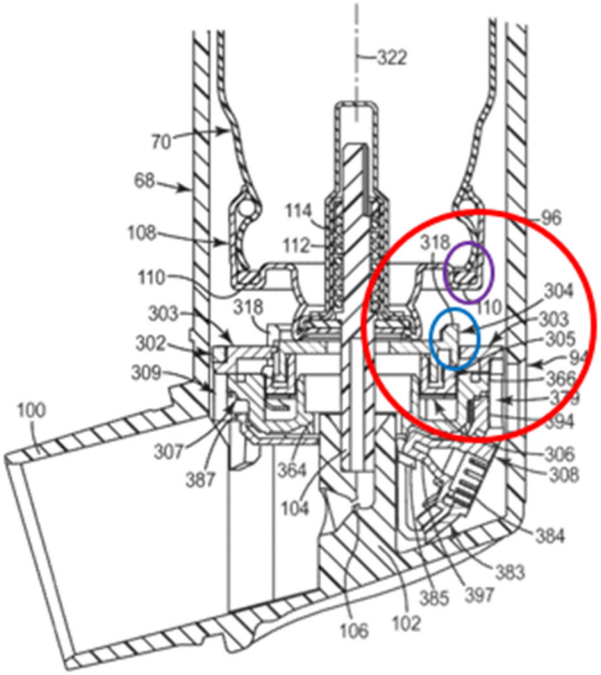


FIG. 27

116. As discussed above, I have reviewed each of Defendants' ANDA Products and determined that the dose counter used by Defendants is disclosed by the '406 Publication. As also discussed above, the Defendants' ANDA Products include an indexer with castellations that is moved when the medicament canister is depressed by the user. I understand that Plaintiffs contend that the "castellations of the indexer" in the Defendants' ANDA Products is an "actuation member" or "actuation members." *See* Plaintiffs' Infringement Contentions to Cipla at Appendix 1, p. 9.[4]

[4] Throughout this Report I refer to contentions Plaintiffs have made in their infringement contentions to Defendants. My reference thereto should not be construed as agreement with the contentions. I am merely identifying what Plaintiffs have asserted. I also reserve my right to

Assuming Plaintiffs correctly identify the indexer in the Defendants' ANDA Products as an "actuation member," then the '406 Publication discloses this limitation.

117. I understand that the Parties have disputed the meaning of actuation member. To the extent that the Court adopts Plaintiffs' construction ("a component of the dose counter's actuator that transmits motion from the canister to the actuator") and Plaintiffs contend that the castellations of the indexer, or any part thereof, in the Defendants' ANDA Products is an "actuation member," then my opinion that the '406 Publication discloses this limitation remains the same.

118. To the extent that the Court adopts Defendants' proposed construction ("pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"), if Plaintiffs contend that a single castellation of the indexer is a "pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count," then my opinion that the '406 Publication discloses this limitation remains the same. To the extent that Plaintiffs contend that the castellations of the indexer, or any part thereof, is not literally included in the Defendants' ANDA Product, but that the castellations of the indexer, or any part thereof is equivalent to a "pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count," then my opinion remains that the '406 Publication discloses this limitation as broadened by the Doctrine of Equivalents, because the dose counter in the Defendants' ANDA Products are disclosed by the '406 Publication.

119. ***Limitation 1D: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and."***

respond to actual infringement arguments, to the extent any are made in Plaintiffs' expert reports on infringement.

The ’406 Publication discloses canister housings with an inner wall. *See, e.g.,* Fig. 27 (shown with red lines below).

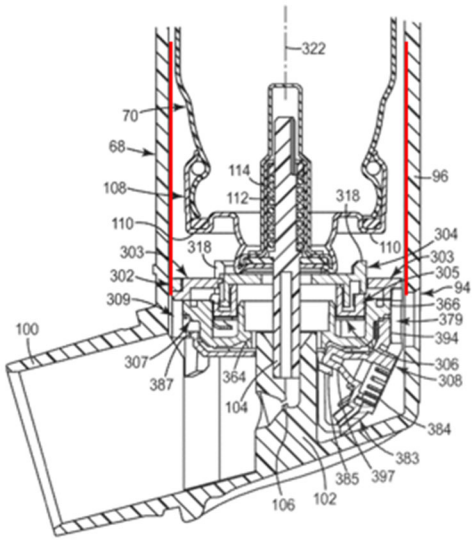


FIG. 27

120. In addition, the ’406 Publication discloses that the dose counter housing includes two forward legs (378) which mate with “interior surfaces of the actuator housing for the aerosol container 70.” *See, e.g., id.* at [00143]; *See also, e.g.,* [00100], [00119]. In order to “mate” there must be a formation extending inwardly from a main surface of the inner wall. Such a formation would act as a canister support formation.

121. ***Limitation 1E: “wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.”*** The ’406 Publication discloses a canister housing having a longitudinal axis X (axis 322) which passes through the center of the central outlet port. *See, e.g.,* ’406 Publication at Figs. 21 and 27.

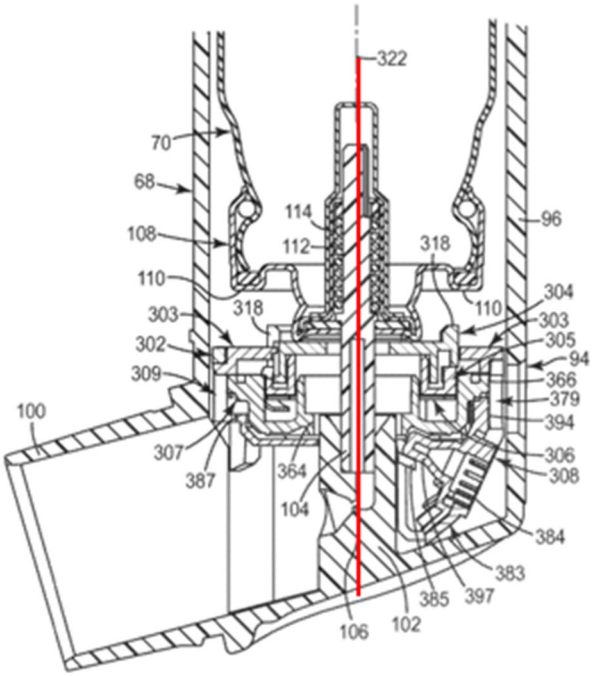
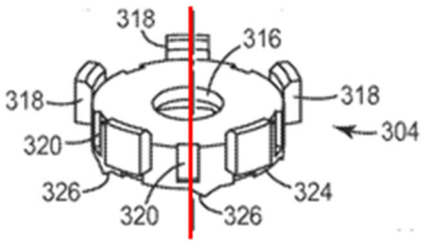


FIG. 27

122. As discussed above, I understand that Plaintiffs have identified the "castellations of the indexer" as the alleged actuation member(s) in the Defendants' ANDA Products. *See* Plaintiffs' Infringement Contentions to Cipla at Appendix 1, p. 9.

123. As shown below, the "castellations of the indexer" encircle the axis and central outlet port. To the extent Plaintiffs argue that all castellations of the indexer together are the actuation member(s), any support structure will necessarily lie in a common plane with the central outlet port, the indexer, and an inner wall canister support structure because the axis and central outlet port are encircled by the actuation members.



124. To the extent Plaintiffs contend that a single castellation of the indexer is the actuation member(s), the '406 Publication discloses this limitation. As can be seen in Fig. 28, leg 378, which mates with a support rail (as discussed above), aligns with castellation 318, the central outlet port and longitudinal axis X (red dashed line).

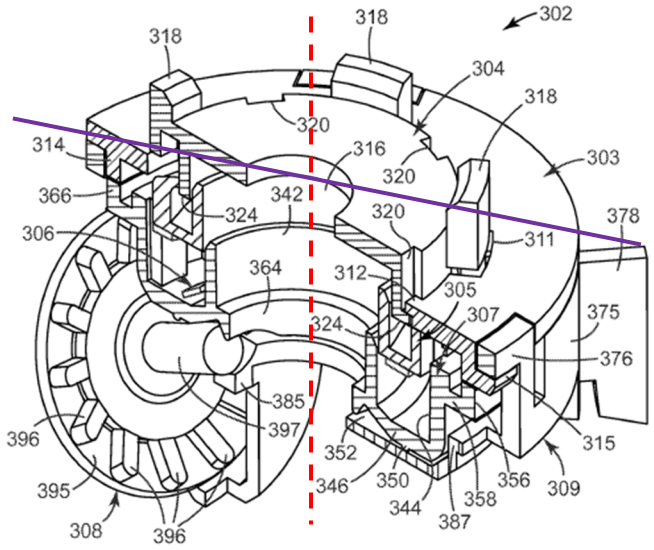


FIG. 28

125. I understand that the Parties' dispute the meaning of the phrase "[lying or lie] in a common plane coincident with the longitudinal axis X." I understand that the difference between the Parties' construction is that Defendant's proposal requires that the canister support formation be directly adjacent to the actuation member. As shown in Figure 28 above, the '406 Publication discloses a support formation (mated with leg 378) located directly adjacent to a castellation (318), which I understand Plaintiffs contend is the actuation member. My opinion remains the same under Plaintiffs' construction, which does not require the actuation member to be directly adjacent to the support formation.

126. For all of these reasons, it is my opinion that the '406 Publication anticipates claim 1 of the '289 Patent.

127. Claim 2 depends from claim 1 and recites, "the inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter." The '406 Publication discloses the medicament canister (aerosol container) is contained in the actuator housing, and the medication is dispensed by pressing down on the aerosol container relative to the actuator housing and opening the valve. *See, e.g.,* '406 Publication at 150; *see also, e.g.,*[00135], [00149], [00104], [00106]. The dose counter is clipped within the actuator housing. *See, e.g., id.* at [00105]. Thus, when the medicament canister moves relative to the actuator housing, it similarly moves relative to the dose counter. For at least these reasons, claim 2 is anticipated by the '406 Publication.

128. Claim 3 depends from claim 1 and recites, "the inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." The '406 Publication discloses a lid 303 with radial hole extensions 311 through which castellations 318 of indexer 304 extend. *See, e.g.,* 406 Publication at [00136], Fig. 24. The dose counter in the Defendants' ANDA Products contains a lid with slots through which castellations extend. I understand that Plaintiffs contend that the lid is equivalent to the claimed "inner wall through which the actuation member extends." *See* Plaintiffs' Infringement Contentions to Cipla at Appendix 1, p. 24. Because the lid, slots and castellations are the same in both the '406 Publication and the dose counter in the Defendants' ANDA Products, to the extent the claims encompass the Defendants' ANDA Products under the Doctrine of Equivalents, they similarly encompass the disclosures of the '406 Publication. For at least these reasons, Claim 3 is anticipated by the '406 Publication.

(ii) *Claims 1-3 and 12 of the '587 Patent are Anticipated by the '406 Publication*

129. In my opinion, claims 1-3 and 12 of the '587 Patent are invalid at least because they are anticipated under 35 U.S.C § 102(b) by the '406 Publication.

130. Claims 1-10 and 12 of the '587 Patent overlap Claims 1-10 of the '289 Patent. Claim 1 of the '587 Patent differs from Claim 1 of the '289 Patent only in the additional requirement that the "first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler." *Compare* '289 Patent, Claim 1 with '587 Patent, Claim 1. Claim 12 of the '587 Patent differs from Claim 1 of the '289 Patent only in the additional requirement that the "first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member." *Compare* '289 Patent, Claim 1 with '587 Patent, Claim 12.

131. In addition, the prosecution history confirms that there are no substantive differences between claims 1-10 of the '289 Patent and claims 1-10 and 12 of the '587 Patent. I understand that, during prosecution of the '587 Patent, the Examiner explicitly determined that the additional language reciting "purpose" in claims 1 and 12 did not carry any patentable weight. *See* '587 Patent Prosecution History, February 7, 2017 Office Action at 3; *see also, e.g.,* M.P.E.P. § 2114.II (citing *Ex parte Masham*, 2 U.S.P.Q.2d 1647 (Bd. Pat. App. & Inter. 1987) ("A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim."). Thus, the language stating purpose does not distinguish claims 1 and 12 of the '587 Patent from claim 1 of the '289 Patent.

132. Accordingly, because claims 1-3 and 12 of the '587 Patent are essentially identical to claims 1-3 of the '289 Patent, they are anticipated by the '406 Publication for the same reasons set forth in Section XV.A.(i), above.

133. In addition, even if reciting the purpose added an element to the claims, the '406 Publication discloses the purpose recited in claims 1 and 12. As discussed above, the '406 Publication discloses every structural element of the Claims 1 and 12, therefore the inhaler and dose counter disclosed therein would inherently perform the recited purpose, thereby anticipating claims 1-3 and 12 of the '587 Patent.

B. The Asserted Claims of the Common Plane Patents are Anticipated by the '514 Publication

(i) *Claims 1 and 4-8 of the '289 Patent are Anticipated by the '514 Publication*

134. In my opinion, claims 1 and 4-8 of the '289 Patent are invalid at least because they are anticipated under 35 U.S.C § 102(b) by the '514 Publication.

135. Claim 1 is the only independent claim of the '289 Patent. Claims 4-8 depend, either directly or indirectly, from Claim 1. Claim 1 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

'289 Patent, claim 1.

136. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** To the extent the preamble is limiting, the '514 Publication discloses an inhaler for metered dose inhalation. *See, e.g.,* '514 Publication at 14:4-19 (disclosing "adaptor 20").

137. ***Limitation 1A: "a main body having a canister housing."*** The inhaler disclosed in the '514 Publication has a main body with a canister housing. *See, e.g., id.* at 10:16-19; 14:4-19 (disclosing "generally cylindrical portion 25" and "chamber 26").

138. ***Limitation 1B: "a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and."*** The '514 Publication discloses a medicament canister (container 1), which is moveable relative to the canister housing. *See, e.g., id.* at 14:4-19 ("Fig. 2a illustrates a ***conventional*** adaptor used for press-and-breathe type inhalers" (emphasis added)). The medicament canister (container 1) is retained in a central outlet port of the canister housing (support block 21 having socket 22) arranged to mate with a canister fire stem (outlet member 5) of the medicament canister. *Id.*; Figs. 1a, 2a.

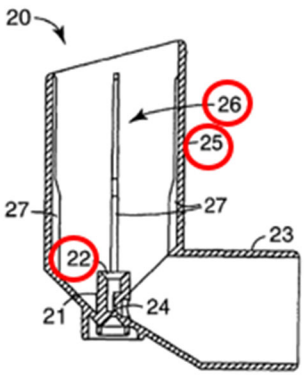


Fig. 2a

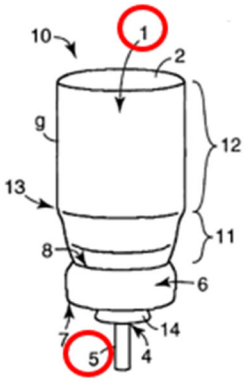


Fig. 1a

139. ***Limitation 1C: "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** The '514 Publication discloses incorporating a dose counter into the inhaler for metered dose inhalation. *See, e.g., id.* at 15: 8-14 (annular dose indicator 50); Fig. 4, 8b. The '514 Publication further discloses dose counters having actuation members having at least a portion thereof located in the canister housing. *See, e.g.,* Figs 8a and 9c (actuation pin 29 or 2g or 23 and

inclined receiving surface 96 or 36). The actuation member is operated by movement of the medicament canister. *Id*.

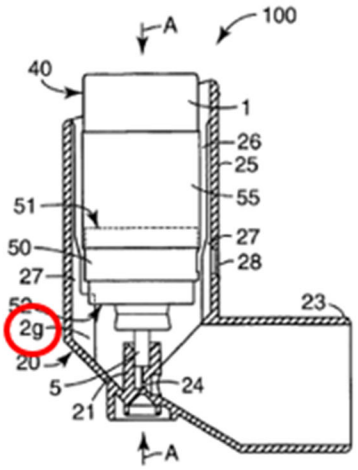


Fig. 8a

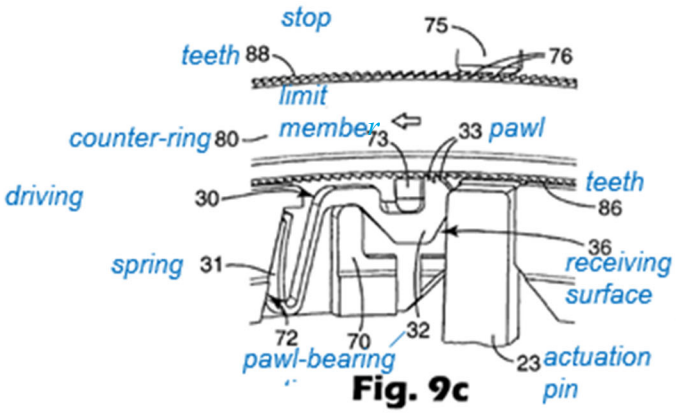


Fig. 9c

140. When the canister is depressed, the downward movement moves the dose indicator towards actuation pin (29, 2g or 23). This movement causes the actuation pin to move relative to the dose indicator along the receiving surface (96 or 36) of the driving member (90).

141. I understand that the Parties have disputed the meaning of actuation member. Whether the Court adopts Plaintiffs' construction ("a component of the dose counter's actuator that transmits motion from the canister to the actuator") or Defendants' proposed construction ("pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"), my opinion that the '514 Publication discloses this limitation remains the same.

142. ***Limitation 1D: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and."*** The '514 Publication discloses a canister housing with an inner wall. *See, e.g.*, Fig. 2a. In addition,

the '514 discloses support ribs (27) which extend inwardly from the main surface of the inner wall. *See, e.g., id.* , *see also, e.g., id.* at 25:19-22 and Figs. 11a, 12a.

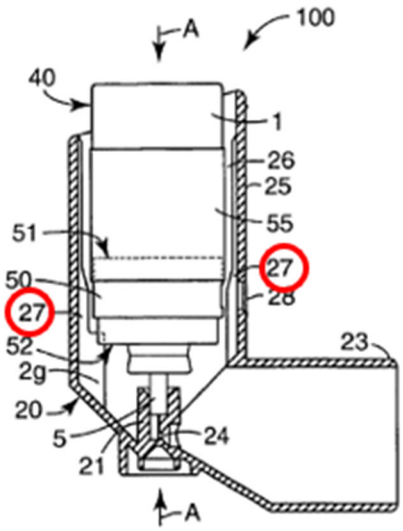


Fig. 8a

143. ***Limitation 1E: "wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X."*** The '514 Publication discloses a longitudinal axis A (axis A) which passes through the center of the central outlet port. *See, e.g.,* Figs. 2a, 8a. In addition, as shown in Figure 8 below, the first inner wall canister support formation (rib 27), the actuation member (actuation pin 29), and the central outlet port (socket 22) lie in a common plane coincident with the longitudinal axis X.

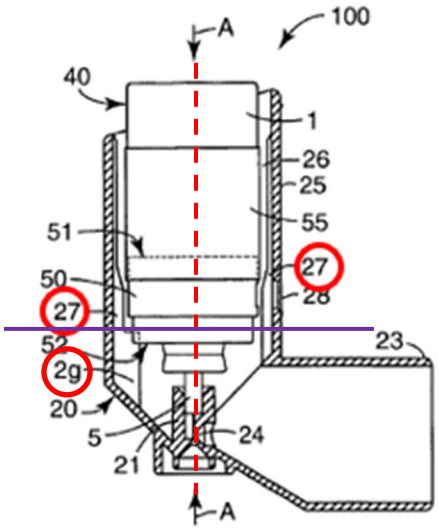


Fig. 8a

Furthermore, as can be seen in Figure 8a, the actuation pin (29 or 2g) is an inward extension of the rib 27. Thus, the first inner wall canister support formation, actuation member, and central outlet port of the '514 Publication all lie in a single plane that is coincident with the longitudinal axis A that passes through the central outlet port.

144. In addition, the driving member 90 or the receiving surface 96 of the driving member 90 may also be considered actuation members. At least a portion of this driving member 90 and the receiving surface 96, which can act to actuate the dose counter when depressed by the canister, lie in the same plane as actuation pin 29. Therefore, that portion of the driving member 90 or the receiving surface 96 of the driving member 90 that lies in the same plane as actuation pin 29 can be considered the actuation member as recited in Claim 1 of the '289 Patent. The portion of this driving member 90 and the receiving surface 96 that lies in the same plane as actuation pin 29 therefore lies in the same plane as the rib 27 and longitudinal axis A.

145. I understand that the Parties' dispute the meaning of the phrase "[lying or lie] in a common plane coincident with the longitudinal axis X." I understand that the difference between

the Parties' constructions is that Defendants' proposal requires that the canister support formation be directly adjacent to the actuation member. As shown in Figure 8a above, the '514 Publication discloses a support formation (21) located directly adjacent to the actuation pin (2g). My opinion remains the same under Plaintiffs' construction, which does not require the actuation member to be directly adjacent to the support formation.

146. For all of these reasons, it is my opinion that the '514 Publication anticipates claim 1 of the '289 Patent.

147. Claim 4 of the '289 Patent depends from claim 1 of the '289 Patent and recites "the inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." As can be seen in Figure 2a below, the '514 Publication discloses rib 27, which extends longitudinally along an inside surface of the main body. Figure 2a is shown alongside Figure 7C of the '289 Patent, confirming that the rib extends longitudinally long an inside surface of the main body.

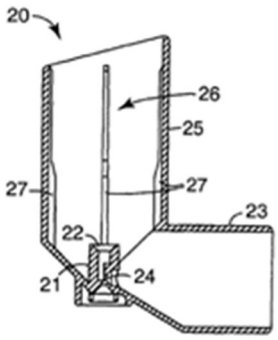


Fig. 2a

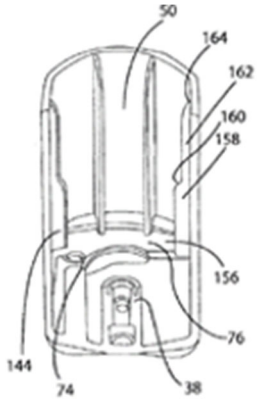


FIG. 7C

148. For at least these reasons, claim 4 is anticipated by the '514 Publication.

149. Claim 5 of the '289 Patent depends from claim 4 of the '289 Patent and recites "the inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." As can be seen in Figure 2a, the '514 Publication discloses a support rail with a step formed thereon (circled in red). For comparison, the '289 Patent discloses similar structures as support rails with a step formed thereon.

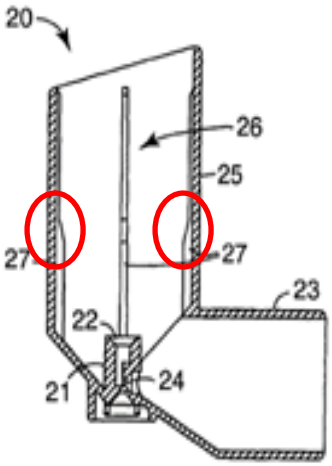


Fig. 2a

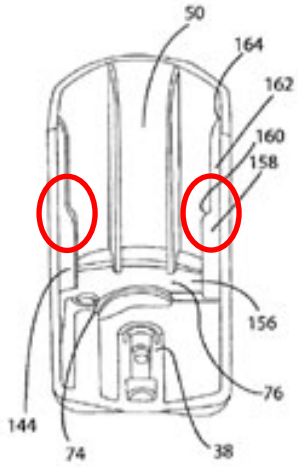


FIG. 7C

150. I understand that the Parties dispute the construction of "step formed thereon." Whether the Court adopts Plaintiffs' proposed construction ("a location of changing width dimension thereon") or Defendants' proposed construction ("a stepwise increase in the extent to which the support rail extends inwardly") my opinion that the '514 Publication discloses this limitation remains the same. For at least these reasons, claim 5 is anticipated by the '514 Publication.

151. Claim 6 of the '289 Patent depends from claim 4 of the '289 Patent and recites "the inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." As can be seen in Figure 2a, the '514

Publication discloses a plurality of support rails extending longitudinally along an inside surface of the main body. For at least these reasons, claim 6 is anticipated by the '514 Publication.

152. Claim 7 of the '289 Patent depends from claim 6 of the '289 Patent and recites "the inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." As can be seen in Figure 2a, the '514 Publication discloses a plurality of support ribs (27) positioned diametrically opposite each other.

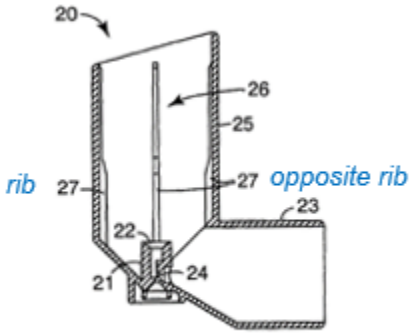


Fig. 2a

153. I understand that the Parties dispute the construction of "positioned at opposite ends of the inside surface of the main body to face each other." I understand that the difference between Plaintiffs' proposed construction ("located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other") and Defendants' proposed construction ("positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail") is that Defendants construe "opposite ends" to mean diametrically opposed, while Plaintiffs' construction merely requires the support rails to be on opposite sides. Because the '514 Publication discloses a plurality of support rails meeting Defendants' construction, my opinion that the '514 Publication discloses this limitation remains the same

irrespective of which construction the Court adopts. For at least these reasons, claim 7 is anticipated by the '514 Publication.

154. Claim 8 of the '289 Patent depends from claim 4 of the '289 Patent and recites "the inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." As can be seen in Figure 2a, the '514 Publication discloses support rails (27) with two steps formed thereon, where the steps are longitudinally spaced along an inside surface of the main body. For comparison, Figure 7C from the '289 Patent identifies similar structures as "steps" on the support rail. *See* '289

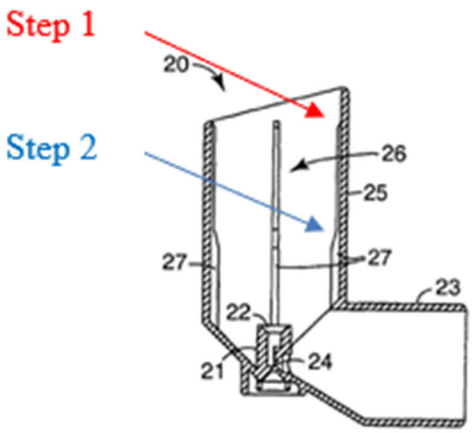


Fig. 2a

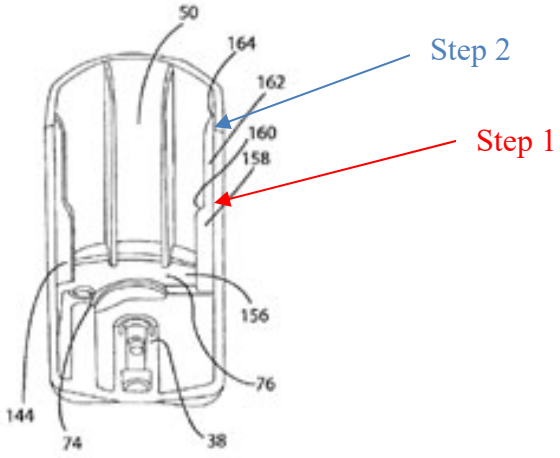


FIG. 7C

Patent at 15:65-16:3 (identifying first step 160 and second step 164).

155. I understand that the Parties dispute the construction of "step formed thereon." Whether the Court adopts Plaintiffs' proposed construction ("a location of changing width dimension thereon") or Defendants' proposed construction ("a stepwise increase in the extent to which the support rail extends inwardly") my opinion that the '514 Publication discloses this limitation remains the same. For at least these reasons, claim 8 is anticipated by the '514 Publication.

(ii) *Claims 1, 4-8 and 11-12 of the '587 Patent are Anticipated by the '514 Publication*

156. In my opinion, claims 1, 4-8, 11, and 12 of the '587 Patent are invalid at least because they are anticipated under 35 U.S.C § 102(b) by the '514 Publication.

157. As discussed above, claims 1-10 and 12 of the '587 Patent overlap with claims 1-10 of the '289 Patent. Thus, because claims 1, 4-8, and 12 of the '587 Patent are essentially identical to claims 1 and 4-8 of the '289 Patent, they are anticipated by the '514 Publication for the same reasons set forth in Section XV.B.(i), above.

158. In addition, even if reciting the purpose added an element to the claims, the '514 Publication discloses the purpose recited in claims 1 and 12. As discussed above, the '514 Publication discloses every structural element of the Claims 1 and 12, therefore the inhaler and dose counter disclosed therein would inherently perform the recited purpose, thereby anticipating claims 1, 4-8 and 12 of the '587 Patent.

159. Claim 11 of the '587 Patent depends from claim 1 of the '587 Patent and recites "the inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X." As discussed above in connection with claim 1 of the '289 Patent, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X. In addition, as discussed in connection with claim 7 of the '289 Patent, the '514 Publication discloses ribs (27) that are diametrically opposed. Thus, as shown in Figure 8a below, the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.

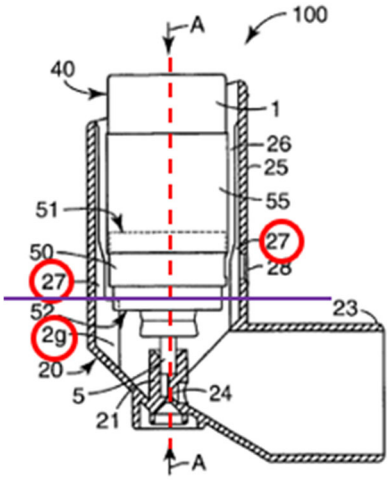


Fig. 8a

160. I understand that the Parties' dispute the meaning of the phrase "[lying or lie] in a common plane coincident with the longitudinal axis X." I understand that the difference between the Parties' constructions is that Defendant's proposal requires that the canister support formation be directly adjacent to the actuation member. As shown in Figure 8a above, the '514 Publication discloses a support formation (21) located directly adjacent to the actuation pin (2g). My opinion remains the same under Plaintiffs' construction, which does not require the actuation member to be directly adjacent to the support formation.

161. For at least these reasons, claims 1, 4-8, 11, and 12 are anticipated by the '514 Publication.

C. The Asserted Claims of the Common Plane Patents Would Have Been Obvious Over the '406 Publication

(i) *Claims 1-8 Would Have Been Obvious Over the '406 Publication*

162. In my opinion, claims 1-8 of the '289 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '406 Publication.

163. Claim 1 is the only independent claim of the '289 Patent. Claims 2-8 depend, either directly or indirectly from Claim 1. Claim 1 recites:

An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,
a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

'289 Patent, claim 1. Each limitation of Claim 1 would have been obvious over the '406 Publication.

164. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** As discussed above in Paragraph 112, to the extent the preamble is limiting, the '406 Publication discloses this limitation.

165. ***Limitation 1A: "a main body having a canister housing."*** As discussed above in Paragraph 113, the '406 Publication discloses this limitation.

166. ***Limitation 1B: "a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and."*** As discussed above in Paragraph 114, the '406 Publication discloses this limitation.

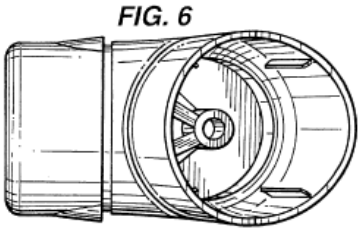
167. ***Limitation 1C: "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** As discussed above in Paragraphs 115-118, the '406 Publication discloses this limitation.

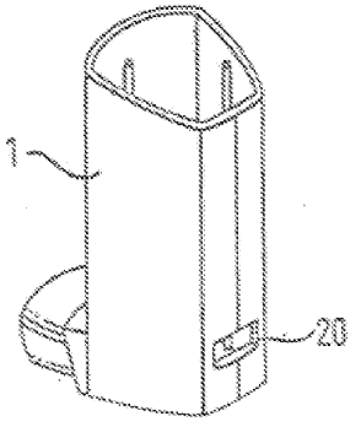
168. ***Limitation 1D: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and."*** As discussed above in Paragraphs 119-120, the '406 Publication discloses this limitation.

169. To the extent that the '406 Publication does not disclose this limitation, it would have been obvious to a POSA to select a canister housing for use with the dose counter of the '406 Publication that included inner wall canister support formations (i.e., ribs). As of the earliest priority date, the use of ribs, or "inner wall canister support formations extending inwardly" were essentially ubiquitously used in MDIs. *See, e.g.*, the '998 Publication, the '008 Publication, the '822 Patent, the '668 Patent, the '260 Publication and the '514 Publication. In fact, in 1965 (over 40 years before the earliest priority date of the Asserted Patents) the standard actuator used in inhalers was redesigned to "introduce[] four equally spaced ribs to locate the container, and provide an annular passageway to draw air using the mouthpiece." Lewis at 236. In addition, the "support provided by the modified actuator [and ribs] was introduced to prevent accidental opening of the valve as a result of unintentional axial movement of the valve stem. The updated design remains an important feature of present actuators." *Id*. In addition, to helping stabilize the canister, ribs were known to prevent unwanted gassing of the canisters, where drug product and propellent leak out of the canister due to bending of the valve during insertion and use. Ribs in the canister help guide insertion of the canister straight into the valve stem block, minimizing this unwanted gassing. In addition, by keeping the canister in better alignment, inclusion of ribs aids in the control of tolerances, allowing for more accurate counting when dose counters are included in the device. A person of skill in the art would have been motivated to include this important design feature in any MDI, and in view of the years of evidence indicating the benefits of such ribs, would have had a reasonable expectation of success in including them. In fact, it would have been a

departure from known practice, and less likely to result in a successful product, for a person of skill in the art to select a canister housing that lacked these ribs.

170. The importance of inclusion of ribs is evidenced by at least a half dozen exemplary references pre-dating the earliest priority date of the Asserted Patents, each of which discloses the use of ribs in inhalers.

<table>
<tr>
<td> 

<u>’998 Patent</u>
(1999)</td>
<td> 

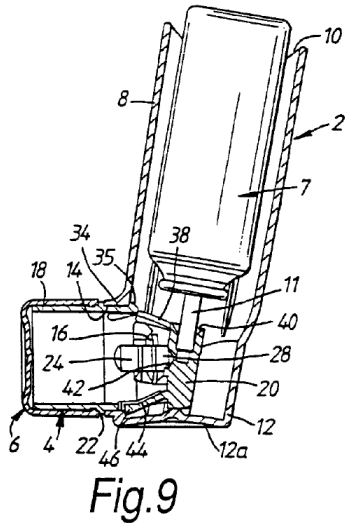
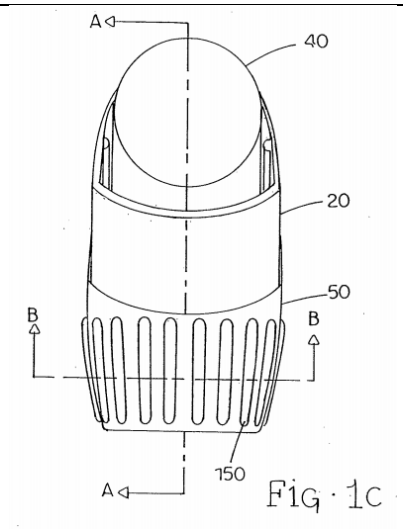
<u>’008 Publication</u>
(2006)</td>
<td>“Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.”
<u>’822 Patent</u>
(1989)</td>
</tr>
<tr>
<td> 

Fig.9
<u>’668 Patent</u></td>
<td> 

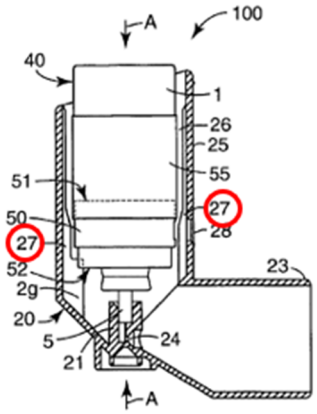
<u>’260 Publication</u>
(2004)</td>
<td> 

Fig. 8a
<u>’514 Publication</u>
(2003)</td>
</tr>
</table>

(2006)		

171. The '406 Publication discloses the use of forward legs (378) which mate with "interior surfaces of the actuator housing for the aerosol container 70." *See, e.g., id.* at [00143]; *See also, e.g.,* [00100], [00119]. In order to "mate" there must be a formation extending inwardly from a main surface of the inner wall (i.e., a rib). Thus, for this reason, and in view of the extensive teachings discussed above, a POSA would have been motivated to use an actuator with ribs in combination with the dose counter disclosed in the '406 Publication. Moreover, the '406 Publication explicitly discloses the compatibility of its inventive dose counter with a variety of standard inhaler housing designs: "[T]he dose counter 2 is designed to be useable with a variety of metering valve designs, and to fit compactly within commercially available actuator housing profiles so that it is not necessary to change the external configuration of those actuator housings to accommodate the inventive dose counter 2 therein." *Id*. at [00105]; *see also, e.g., id*. at [00124] and [00151]. As discussed above, it was standard to include ribs in actuator housing profiles. Therefore, to the extent this limitation is not explicitly disclosed by the '406 Publication a POSA would have found it obvious to select an actuator housing profile with ribs. Therefore, this limitation would have been obvious over the '406 Publication and the knowledge of the POSA.

172. ***Limitation 1E: "wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X."*** As discussed above in Paragraphs 121-125, the '406 Publication discloses this limitation. For all of these reasons, claim 1 would have been obvious over the '406 Publication and the knowledge of the POSA.

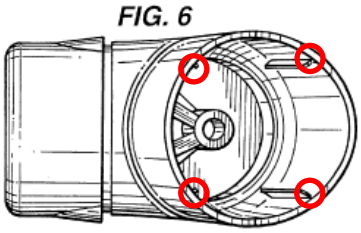
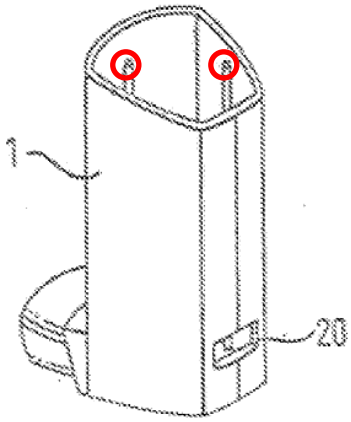
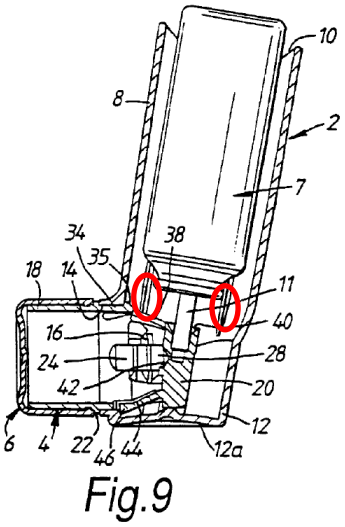
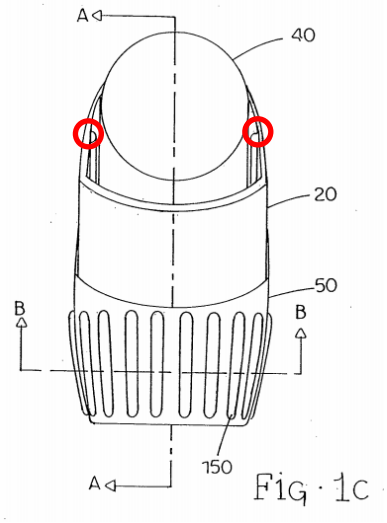
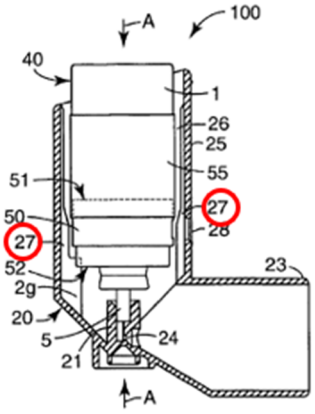
173. Claim 2 depends from claim 1 and recites, "the inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter." As discussed above in Paragraph 127, the '406 Publication discloses this limitation. For at least these reasons, claim 2 would have been obvious over the '406 Publication and the knowledge of the POSA.

174. Claim 3 depends from claim 1 and recites, "the inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." As discussed above in Paragraph 128, the '406 Publication discloses this limitation. For at least these reasons, claim 3 would have been obvious over the '406 Publication and the knowledge of the POSA.

175. Claim 4 of the '289 Patent depends from claim 1 of the '289 Patent and recites "the inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." This limitation would have been obvious over the '406 Publication and the knowledge of the POSA. As discussed above, the use of ribs extending longitudinally along an inside surface of the main body of an inhaler was ubiquitous by 2009. As discussed in connection with claim 1, a POSA would have found it obvious to include ribs in the actuator of the '406 Publication. For at least these reasons, claim 4 would have been obvious over the '406 Publication and the knowledge of the POSA.

176. Claim 5 of the '289 Patent depends from claim 4 of the '289 Patent and recites "the inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." I understand from the '289 Patent, that a step can include the top of the rib. It would be impossible to have a rib that did not have an end, or step, at the top of the inhaler. As shown below, each of the half-dozen exemplary actuators with ribs includes such a step (circled in red). In addition, a

person of skill in the art would have been motivated to select or modify ribs to include tapered or stepped designs to aid in the insertion and removal of the canister, so as to avoid angled insertion, which may cause unwanted gassing of the valve, and to improve tolerance control, fit, and function.

 **'998 Patent** (1999)	 **'008 Publication** (2006)	"Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1." **'822 Patent** (1989)
 Fig.9 **'668 Patent** (2006)	 Fig. 1c **'260 Publication** (2004)	 **Fig. 8a** **'514 Publication** (2003)

Accordingly, Claim 5 would have been obvious over the '406 Publication and the knowledge of the POSA.

177. Claim 6 of the '289 Patent depends from claim 4 of the '289 Patent and recites "the inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." As discussed above the use of a plurality of support rails has been known, and common, since 1965. *See* Lewis at 236. Moreover, a single support rail would not serve the purpose of stabilizing the canister or guiding the insertion of the canister, as discussed above. Thus, the use of a plurality of support rails on the actuator of the '406 Publication would have been obvious to a POSA, particularly in view of the disclosure in the '406 Publication of legs that "mate" with the actuator. For at least these reasons, claim 6 would have been obvious over the '406 Publication and the knowledge of the POSA.

178. Claim 7 of the '289 Patent depends from claim 6 of the '289 Patent and recites "the inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." As discussed above, the use of a plurality of equally spaced support rails has been known, and common, since 1965. *See* Lewis at 236. Equally spaced support rails will necessarily be positioned "at opposite ends to face each other." Moreover, as can be seen in the exemplary prior art actuators shown above, it was common to place support rails "at opposite ends to face each other." Thus, Claim 7 would have been obvious over the '406 Publication and the knowledge of the POSA.

179. Claim 8 of the '289 Patent depends from claim 4 of the '289 Patent and recites "the inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." I understand that Plaintiffs have interpreted step to include both the top of a support rail, and the bottom. As support

rails will necessarily have a beginning and end, it would have been obvious for a POSA to include support rails including two steps formed thereon in the actuator of the '406 Publication. Thus, Claim 8 would have been obvious over the '406 Publication and the knowledge of the POSA.

180. For at least these reasons, claims 1-8 of the '289 Patent would have been obvious over the '406 Publication and the knowledge of the POSA.

(ii) *Claims 1-8 and 11-22 Would Have Been Obvious Over the '406 Publication*

181. In my opinion, claims 1-8 and 11-22 of the '587 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '406 Publication.

182. Because claims 1-8, and 12 of the '587 Patent are essentially identical to claims 1-8 of the '289 Patent, they would have been obvious over the '406 Publication for the same reasons set forth in Section XV.C.(i), above.

183. In addition, even if reciting the purpose added an element to the claims, the '406 Publication alone, or in combination with the '514 Publication, discloses the purpose recited in claims 1 and 12. As discussed above, the '406 Publication discloses, or renders obvious, every structural element of the Claims 1 and 12, therefore the inhaler and dose counter disclosed therein would inherently perform the recited purpose, thereby rendering obvious claims 1-8 and 12 of the '587 Patent.

184. Claim 11 of the '587 Patent depends from claim 1 of the '587 Patent and recites "the inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X." As discussed above in connection with claim 1 of the '289 Patent, the '406 Publication discloses, or renders obvious, a first inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident

with longitudinal axis X. In addition, as discussed in connection with claim 7 of the '289 Patent, since 1965 it was common to include equally spaced (e.g., diametrically opposed) ribs. Thus, to the extent not explicitly disclosed, it would have been obvious to modify the actuator of the '406 Publication to include a second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator to include ribs, as claimed, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Thus, Claim 11 would have been obvious over the '406 Publication and the knowledge of the POSA.

185. Claim 13 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

'587 Patent, claim 13.

186. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** As discussed above in Paragraph 112, to the extent the preamble is limiting, the '406 Publication discloses this limitation.

187. ***Limitation 13A: "a main body having a canister housing."*** As discussed above in Paragraph 113, the '406 Publication discloses this limitation.

188. ***Limitation 13B: "a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** As discussed above in Paragraphs 114-118, the '406 Publication discloses this limitation.

189. ***Limitation 13C: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall."*** As discussed above in Paragraph 119-120, the '406 Publication discloses this limitation. To the extent this limitation is not explicitly disclosed by the '406 Publication, as discussed in Paragraphs 169-170, it would have been obvious in view of the knowledge of the POSA. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator to include ribs, as claimed, and expected success in doing so, for the same reasons discussed in Section XV.C.(i).

190. ***Limitation 13D: "wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and."*** As discussed above in Paragraph 128, the '406 Publication discloses this limitation.

191. ***Limitation 13E: "wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture."*** I understand that Plaintiffs allege that a rail (specifically the rail to which the leg (378) in Defendants' ANDA Products mates) that extends to the lid/housing of the Defendants' ANDA Products is an inner wall cannister support formation that "extends from the main surface of the inner wall to the aperture." *See* Plaintiffs' Infringement Contentions to Cipla, Appendix 2 at 90. As discussed in detail above, the '406 Publication discloses the same lid and housing and similar legs (378) which mate with the inner

wall. Accordingly, to the extent Plaintiffs contend that the Defendants' ANDA Products meet this limitation, so does the '406 Publication. Thus, Claim 13 would have been obvious over the '406 Publication and the knowledge of the POSA.

192. Claim 14 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter." As discussed above in Paragraph 127, the '406 Publication discloses this limitation. Thus, Claim 14 would have been obvious over the '406 Publication and the knowledge of the POSA.

193. Claim 15 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." As discussed above in Paragraph 175, the '406 Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 15 would have been obvious over the '406 Publication and the knowledge of the POSA.

194. Claim 16 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon." As discussed above in Paragraph 176, the '406 Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 16 would have been obvious over the '406 Publication and the knowledge of the POSA.

195. Claim 17 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body." As discussed above in Paragraph 177, the '406 Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 17 would have been obvious over the '406 Publication and the knowledge of the POSA.

196. Claim 18 of the '587 Patent depends from Claim 17 and recites "the inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." As discussed above in Paragraph 178, the '406 Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 18 would have been obvious over the '406 Publication and the knowledge of the POSA.

197. Claim 19 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body." As discussed above in Paragraph 182, the '406 Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 19 would have been obvious over the '406 Publication and the knowledge of the POSA.

198. Claim 20 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture." As discussed above in Paragraphs 121-125, 169-170, the '406 Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 20 would have been obvious over the '406 Publication and the knowledge of the POSA.

199. Claim 21 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port." As discussed above in Paragraph 121-125, the '406

Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 21 would have been obvious over the '406 Publication and the knowledge of the POSA.

200. Claim 22 of the '587 Patent depends from Claim 21 of the '587 Patent and recites "the inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X. As discussed above in Paragraph 184 the '406 Publication in view of the knowledge of the POSA renders this limitation obvious. Thus, Claim 22 would have been obvious over the '406 Publication and the knowledge of the POSA.

201. For at least these reasons, claims 1-8 and 11-22 of the '587 Patent would have been obvious over the '406 Publication and the knowledge of the POSA.

D. The Asserted Claims of the Common Plane Patents Would Have Been Obvious Over the '514 Publication in Combination with '406 Publication

(i) *Claims 1-8 of the '289 Patent Would Have Been Obvious Over the '514 Publication with the '406 Publication*

202. In my opinion, claims 1-8 of the '289 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '514 Publication with the '406 Publication.

203. Claim 1 is the only independent claim of the '289 Patent. Claims 2-8 depend, either directly or indirectly, from Claim 1. Claim 1 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

'289 Patent, claim 1.

204. Each limitation of Claim 1 would have been obvious over the '514 Publication in combination with the '406 Publication.

205. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** As discussed above in Paragraph 136, to the extent the preamble is limiting, the '514 Publication discloses this limitation.

206. ***Limitation 1A: "a main body having a canister housing."*** As discussed above in Paragraph 137, the '514 Publication discloses this limitation.

207. ***Limitation 1B: "a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and."*** As discussed above in Paragraph 138, the '514 Publication discloses this limitation.

208. ***Limitation 1C: "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** As discussed above in Paragraph 139-140, the '514 Publication discloses this limitation. As discussed above in Paragraphs 115-18, the '406 Publication discloses a dose counter meeting this limitation for inclusion in known actuators such as the '514 Publication.

209. ***Limitation 1D: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and."*** As discussed above in Paragraph 142, the '514 Publication discloses this limitation.

210. ***Limitation 1E: "wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X."*** The actuator of the '514 Publication combined with the dose counter of the '406 Publication discloses this limitation. As discussed in Paragraphs 143-145, the '514 Publication discloses a canister housing with a longitudinal axis X passing through a central outlet port with inner wall canister support formations. As discussed in Paragraphs 121-125, when the dose counter of the '406 Publication is incorporated into an actuator, including an actuator as disclosed in the '514 Publication, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X. Accordingly, in my opinion, the combination of the actuator of the '514 Publication with the dose counter of the '406 Publication, discloses this limitation. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '406 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Thus, Claim 1 would have been obvious over the '514 Publication in combination with the '406 Publication.

211. Claim 2 depends from claim 1 and recites, "the inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter." As discussed above in Paragraph 127, the '406 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '406 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 2 would have been obvious over the '514 Publication in combination with the '406 Publication.

212. Claim 3 depends from claim 1 and recites, "the inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." As discussed above in Paragraph 128, the '406 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '406 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 3 would have been obvious over the '514 Publication in combination with the '406 Publication.

213. Claim 4 of the '289 Patent depends from claim 1 and recites "the inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." As discussed above in Paragraph 147, the '514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '406 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 4 would have been obvious over the '514 Publication in combination with the '406 Publication.

214. Claim 5 of the '289 Patent depends from claim 4 and recites "the inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." As discussed above in Paragraphs 149-150, the '514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '406 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 5 would have been obvious over the '514 Publication in combination with the '406 Publication.

215. Claim 6 of the '289 Patent depends from claim 4 and recites "the inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." As discussed above in Paragraph 151, the '514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '406

Publication and the actuator of the ’514 Publication discloses this limitation. Thus, Claim 6 would have been obvious over the ’514 Publication in combination with the ’406 Publication.

216. Claim 7 of the ’289 Patent depends from claim 6 and recites “the inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other.” As discussed above in Paragraphs 152-153, the ’514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the ’406 Publication and the actuator of the ’514 Publication discloses this limitation. Thus, Claim 7 would have been obvious over the ’514 Publication in combination with the ’406 Publication.

217. Claim 8 of the ’289 Patent depends from claim 4 and recites “the inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.” As discussed above in Paragraphs 154-155, the ’514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the ’406 Publication and the actuator of the ’514 Publication discloses this limitation. Thus, Claim 8 would have been obvious over the ’514 Publication in combination with the ’406 Publication.

218. For at least these reasons, claims 1-8 of the ’289 Patent would have been obvious over the ’514 Publication and the ’406 Publication.

(ii) *Claims 1-8 and 11-22 of the ’587 Patent Would Have Been Obvious Over the ’514 Publication in Combination with the ’406 Publication*

219. In my opinion, claims 1-8 and 11-22 of the ’587 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the ’406 Publication.

220. Because claims 1-8 and 12 of the ’587 Patent are essentially identical to claims 1-8 of the ’289 Patent, they would have been obvious over the ’514 Publication in combination with ’406 Publication for the same reasons set forth in Section XV.D.(i)., above.

221. In addition, even if reciting the purpose added an element to the claims, the '406 Publication in combination with the '514 Publication discloses the purpose recited in claims 1 and 12. As discussed above, the '406 Publication in combination with the '514 Publication discloses every structural element of the Claims 1 and 12, therefore the inhaler and dose counter disclosed therein would inherently perform the recited purpose, thereby rendering obvious claims 1-8 and 12 of the '587 Patent.

222. Claim 11 of the '587 Patent depends from claim 1 and recites "the inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X." As discussed in Paragraphs 137-145 and 152-153, above, in connection with claims 1 and 7 of the '289 Patent, the '514 Publication discloses an actuator with a second inner wall canister support formation and a diametrically opposed first inner wall canister support formation. As discussed in Paragraphs 121-125, above, in connection with claim 1 of the '289 Patent, the combination of the dose counter from the '406 Publication and the actuator of the '514 Publication disclose the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X. Because the inner wall canister support formations of the '514 Publication are evenly spaced, and therefore direct opposites, the second inner wall canister support formation would also lie in the common plane coincident with longitudinal axis X. Accordingly, the actuator of the '514 Publication in combination with the dose counter of the '406 Publication renders this claim obvious. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of

the '406 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Thus, Claim 11 would have been obvious over the '514 Publication in combination with the '406 Publication.

223. Claim 13 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

'587 Patent, claim 13.

224. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** As discussed above in Paragraph 137, to the extent the preamble is limiting, the '514 Publication discloses this limitation.

225. ***Limitation 13A: "a main body having a canister housing."*** As discussed above in Paragraph 138, the '514 Publication discloses this limitation.

226. ***Limitation 13B: "a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** As discussed above in Paragraphs 208-209, the '514 Publication in combination with the '406 Publication discloses this limitation. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as

the ones disclosed in the '514 Publication for use with the dose counter of the '406 Publication, and expected success in doing so, for the same reasons discussed in Section XV.D.(i).

227. ***Limitation 13C: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall."*** As discussed above in Paragraph 142, the '514 Publication discloses this limitation.

228. ***Limitation 13D: "wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and."*** As discussed above in Paragraph 121, the '406 Publication discloses this limitation.

229. ***Limitation 13E: "wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture."*** As discussed above in Paragraph 189, the combination of the '406 Publication and '514 Publication discloses this limitation. Thus, Claim 13 would have been obvious over the '514 Publication in combination with the '406 Publication.

230. Claim 14 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter." As discussed above in Paragraph 211, the combination of the '406 Publication and '514 Publication discloses this limitation. Thus, Claim 14 would have been obvious over the '514 Publication in combination with the '406 Publication.

231. Claim 15 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." As discussed above in Paragraphs 147 and 213, the '514 Publication discloses this limitation. Thus, Claim 15 would have been obvious over the '514 Publication in combination with the '406 Publication.

232. Claim 16 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon." As discussed above in Paragraphs 149-150 and 214, the '514 Publication discloses this limitation. Thus, Claim 16 would have been obvious over the '514 Publication in combination with the '406 Publication.

233. Claim 17 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body." As discussed above in Paragraphs 151 and 215, the '514 Publication discloses this limitation. Thus, Claim 17 would have been obvious over the '514 Publication in combination with the '406 Publication.

234. Claim 18 of the '587 Patent depends from Claim 17 and recites "the inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." As discussed above in Paragraphs 152-153 and 216, the '514 Publication discloses this limitation. Thus, Claim 18 would have been obvious over the '514 Publication in combination with the '406 Publication.

235. Claim 19 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body." As discussed above in Paragraphs 154-155 and 217, the '514 Publication discloses this limitation. Thus, Claim 19 would have been obvious over the '514 Publication in combination with the '406 Publication.

236. Claim 20 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture." As discussed above in Paragraph 121-125, 169-170, the combination of the '406 Publication and '514

Publication discloses this limitation. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '406 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Thus, Claim 20 would have been obvious over the '514 Publication in combination with the '406 Publication.

237. Claim 21 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port." As discussed above in Paragraphs 121-125, 143-145, and 210, the combination of the '406 Publication and '514 Publication discloses this limitation. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '406 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Thus, Claim 21 would have been obvious over the '514 Publication in combination with the '406 Publication.

238. Claim 22 of the '587 Patent depends from Claim 21 and recites "the inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X. As discussed above in Paragraph 184 and 222, the combination of the '406 Publication and '514 Publication discloses this limitation. Thus, Claim 22 would have been obvious over the '514 Publication in combination with the '406 Publication.

239. For all of these reasons, claims 1-8 and 11-22 of the '589 Patent would have been obvious over the '514 Publication in combination with the '406 Publication.

E. The Asserted Claims of the Common Plane Patents Would Have Been Obvious Over the '021 Publication

(i) *Claims 1-8 of the '289 Patent Would Have Been Obvious Over the '021 Publication*

240. In my opinion, claims 1-8 of the '289 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '021 Publication.

241. Claim 1 is the only independent claim of the '289 Patent. Claims 2-8 depend, either directly or indirectly, from Claim 1. Claim 1 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

'289 Patent, claim 1.

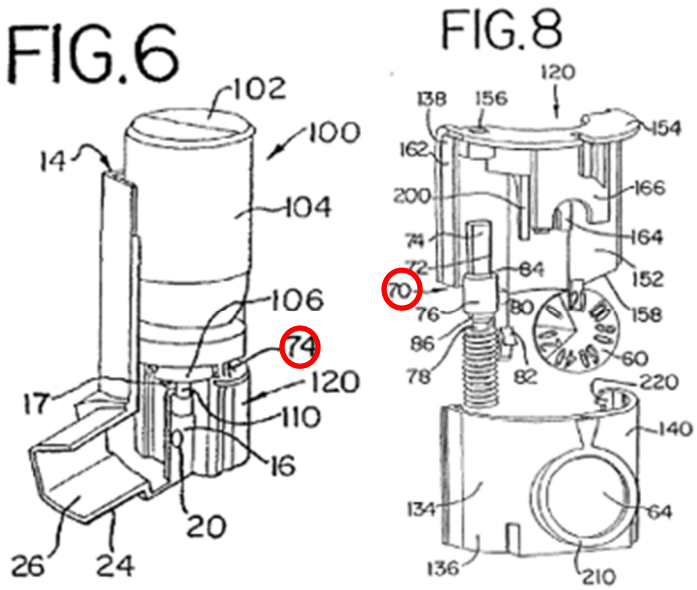
242. Each limitation of Claim 1 would have been obvious over the '021 Publication.

243. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** To the extent the preamble is limiting, this limitation is disclosed by the '021 Publication. *See* '021 Publication at [0007] (disclosing a dispensing device for metered dosages of a substance).

244. ***Limitation 1A: "a main body having a canister housing."*** The '021 Publication discloses a main body having a canister housing. *See id.* at [007], Figs. 1, 2, 5-7.

245. ***Limitation 1B: "a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and."*** The '021 Publication discloses a central outlet port 16 that mates with the stem of a medicament canister 110. *See, e.g., id* at '021 Publication at Figs. 6 and 8, [0076]. The medicament canister is moveable relative to the canister housing. *See id.* at [0011], [0077].

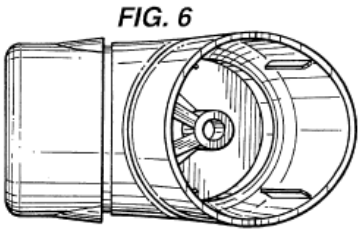
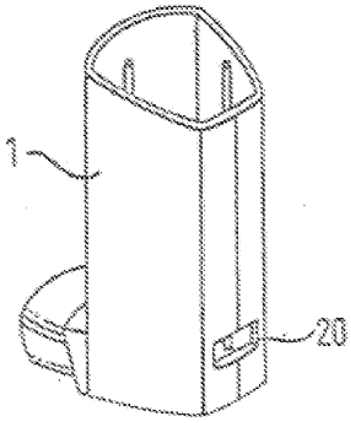
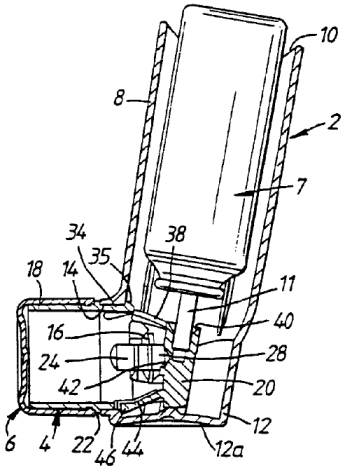
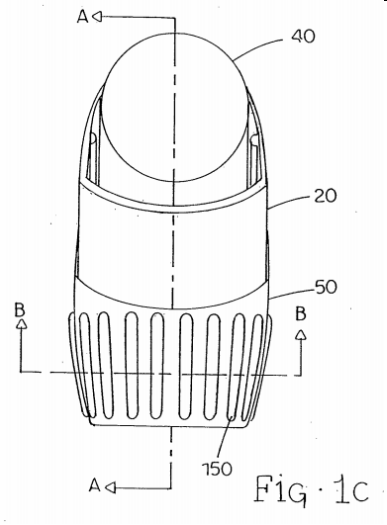
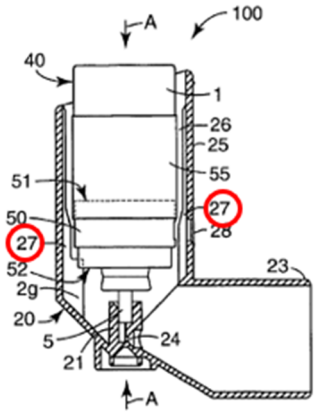
246. ***Limitation 1C: "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** The '021 Publication discloses a dose counter where "an actuator member is mounted in the housing and is responsive to movement of the container." *Id*. at [0011], *see also id* at Figs 6 and 8, [0086], [00115] (disclosing actuation member 70 having upper post 74 which extends into the housing through aperture 56).



When the inhaler disclosed in the '021 Publication is actuated, downward movement of the aerosol container 120 presses down on the upper post 74 of the actuation member 70, causing hook member 82 to engage the ratchet wheel and rotate it. *Id*. at Figs. 6 and 8, [0088].

247. ***Limitation 1D: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and."*** To the extent that the '021 Publication does not disclose this limitation, it would have been obvious to a POSA. As of the earliest priority date, the use of ribs, or "inner wall canister support formations extending inwardly" were essentially ubiquitously used in MDIs. *See, e.g.*, the '998 Publication, the '008 Publication, the '822 Patent, the '668 Patent, the '260 Publication and the '514 Publication. In fact, in 1965 (over 40 years before the earliest priority date of the Asserted Patents) the standard actuator used in inhalers was redesigned to "introduce[] four equally spaced ribs to locate the container, and provide an annular passageway to draw air using the mouthpiece." Lewis at 236. In addition, the "support provided by the modified actuator [and ribs] was introduced to prevent accidental opening of the valve as a result of unintentional axial movement of the valve stem. The updated design remains an important feature of present actuators." *Id*. A POSA would be motivated to include this important design feature in any MDI. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator to include ribs, as claimed, and expected success in doing so, for the same reasons discussed in Section XV.C.(i).

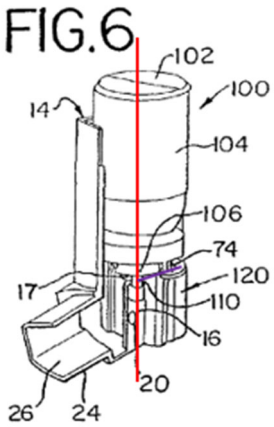
248. The importance of inclusion of ribs is evidenced by at least a half dozen exemplary references pre-dating the earliest priority date of the Asserted Patents, each of which discloses the use of ribs in inhalers.

 **'998 Patent** (1999)	 **'008 Publication** (2006)	"Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1." **'822 Patent** (1989)
 Fig.9 **'668 Patent** (2006)	 **'260 Publication** (2004)	 **Fig. 8a** **'514 Publication** (2003)

249. The '021 Publication discloses spacing the canister from the housing walls. *See, e.g., id.* at [0108], claim 46. A POSA would have been motivated to use an actuator that includes ribs, or to modify the actuator of the '021 Publication to include ribs in order to maintain this space, support the canister, and minimize unwanted counting. *See* Lewis at 236. As discussed above, it

was standard to include ribs in actuator housing profiles. Therefore, a POSA would have found it obvious to select an actuator housing profile with ribs, or modify the actuator of the '021 Publication to include ribs. *See also* Paragraphs 169-170. Therefore, this limitation would have been obvious over the '021 Publication and the knowledge of the POSA.

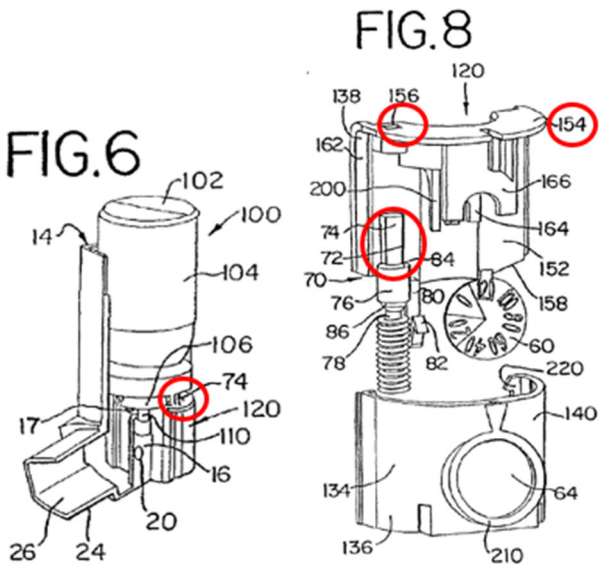
250. ***Limitation 1E: "wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X."*** The '021 Publication also discloses a canister housing having a longitudinal axis X which passes through the center of the central outlet port 16. *See, e.g.,* '021 Publication at Fig. 6 (red line). In addition, as shown in purple, the central outlet port 16 and the actuation member 74 are aligned.



A POSA would be aware that during transportation inhalers are jostled, causing the canister to move within the housing. It would have been obvious to a POSA to position a rib, or canister support formation, adjacent to the actuation member 74 in order to prevent the canister moving in a direction that would allow it to depress the actuation member, which could cause unwanted dose counting. Thus, Claim 1 would have been obvious over the '021 Publication and the knowledge of the POSA.

251. Claim 2 depends from claim 1 and recites, "the inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter." The '021 Publication discloses that the medicament canister is contained in the actuator housing, and the medication is dispensed by pressing down on the aerosol container relative to the dose counter. *See, e.g.,* '021 Publication at [0078], [0088]. Thus, Claim 2 would have been obvious over the '021 Publication and the knowledge of the POSA.

252. Claim 3 depends from claim 1 and recites, "the inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." As shown in the image below, the '021 Publication discloses a housing module with cover 154, through which a portion of the actuation member extends. *See, e.g., F*igs. 6 and 8, [0115].

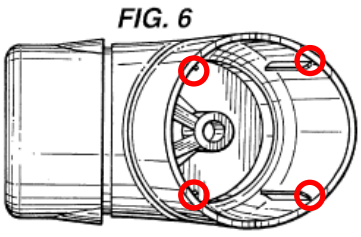
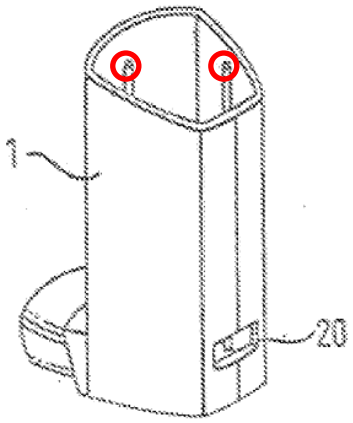


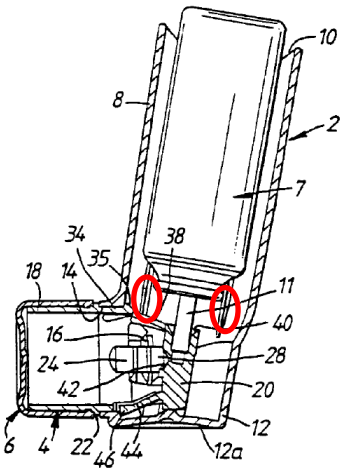
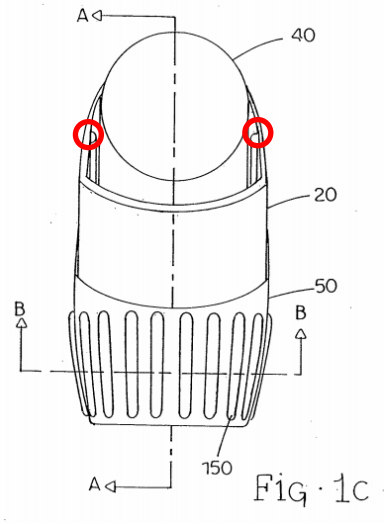
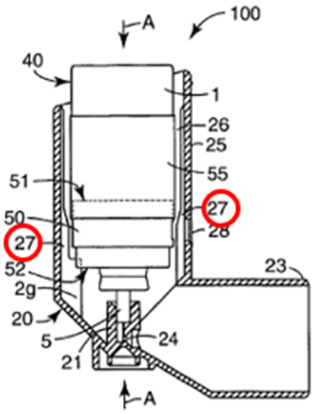
I understand from Plaintiffs' allegations that the gaps or holes in the lid of the Defendants' ANDA Products are equivalent to "apertures formed in the inner wall through which the portion of the actuation member extends" that the claim language must also encompass lids such as the cover

154 disclosed in the ’021 Publication. Accordingly, the ’021 Publication discloses this limitation. Thus, Claim 3 would have been obvious over the ’021 Publication and the knowledge of the POSA.

253. Claim 4 of the ’289 Patent depends from claim 1 and recites “the inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.” As discussed above, the use of ribs extending longitudinally along an inside surface of the main body of an inhaler was ubiquitous by 2009. As discussed in connection with claim 1, a POSA would have found it obvious to include ribs in the actuator of the ’021 Publication. Thus, Claim 4 would have been obvious over the ’021 Publication and the knowledge of the POSA.

254. Claim 5 of the ’289 Patent depends from claim 4 and recites “the inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon.” I understand from the ’289 Patent, that a step can include the top of the rib. It would be impossible to have a rib that did not have an end, or step, at the top of the inhaler. As shown below, each of the half-dozen exemplary actuators with ribs includes such a step (circled in red). In addition, ribs in inhalers commonly included tapered designs to aid in the insertion and removal of the canister, so as to avoid angled insertion, which may cause unwanted gassing of the valve. *See also* Paragraphs 169-170, 176.

 **’998 Patent** (1999)		“Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.” **’822 Patent** (1989)

	’008 Publication (2006)	
 Fig.9 **’668 Patent** (2006)	 Fig. 1C **’260 Publication** (2004)	 **Fig. 8a** **’514 Publication** (2003)

Thus, Claim 5 would have been obvious over the ’021 Publication and the knowledge of the POSA.

255. Claim 6 of the ’289 Patent depends from claim 4 and recites “the inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.” As discussed above the use of a plurality of support rails has been known, and common, since 1965. *See* Lewis at 236; *see also* Paragraphs 50-51 and 169-170. The use of a plurality of support rails on the actuator of the ’021 Publication would have been obvious to a POSA, particularly in view of the disclosure in the ’021 Publication of the need for space between the canister and the housing walls. Thus, Claim 6 would have been obvious over the ’021 Publication and the knowledge of the POSA.

256. Claim 7 of the '289 Patent depends from claim 6 and recites "the inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." As discussed above, the use of a plurality of equally spaced support rails has been known, and common, since 1965. *See* Lewis at 236; *see also* Paragraphs 50-51 and 169-170. Equally spaced support rails will necessarily be positioned "at opposite ends to face each other." Moreover, as can be seen in the exemplary prior art actuators shown above, it was common to place support rails "at opposite ends to face each other." Thus, Claim 7 would have been obvious over the '021 Publication and the knowledge of the POSA.

257. Claim 8 of the '289 Patent depends from claim 4 and recites "the inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." I understand that Plaintiffs have interpreted step to include both the top of a support rail, and the bottom. As support rails will necessarily have a beginning and end, it would have been obvious for a POSA to include support rails including two steps formed thereon in the actuator of the '021 Publication. Thus, Claim 8 would have been obvious over the '021 Publication and the knowledge of the POSA.

258. For at least these reasons, claims 1-8 of the '289 Patent would have been obvious over the '021 Publication and the knowledge of the POSA.

(ii) *Claims 1-8 and 11-22 of the '587 Patent Would Have Been Obvious Over the '021 Publication*

259. In my opinion, claims 1-8 and 11-22 of the '587 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '021 Publication

260. Because claims 1-8 and 12 of the '587 Patent are essentially identical to claims 1-8 of the '289 Patent, they would have been obvious over the '021 Publication, for the same reasons set forth in Section XV.E.(i), above.

261. In addition, even if reciting the purpose added an element to the claims, the '021 Publication alone, discloses the purpose recited in claims 1 and 12. As discussed above, the '021 Publication discloses every structural element of claims 1 and 12, therefore the inhaler and dose counter disclosed therein would inherently perform the recited purpose, thereby rendering obvious claims 1-8 and 12 of the '587 Patent.

262. Claim 11 of the '587 Patent depends from claim 1 and recites "the inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X." As discussed above in connection with claim 1 of the '289 Patent, the '021 Publication, in view of the knowledge of the POSA discloses, or renders obvious, a first inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with longitudinal axis X. In addition, as discussed in connection with claim 7 of the '289 Patent, since 1965 it was common to include equally spaced (e.g., diametrically opposed) ribs. Thus, to the extent not explicitly disclosed, it would have been obvious to modify the actuator of the '021 Publication to include a second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Thus, Claim 11 would have been obvious over the '021 Publication and the knowledge of the POSA.

263. Claim 13 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

'587 Patent, claim 13.

264. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** As discussed above in Paragraph 243, to the extent the preamble is limiting, the '021 Publication discloses this limitation.

265. ***Limitation 13A: "a main body having a canister housing."*** As discussed above in Paragraph 244, the '021 Publication discloses this limitation.

266. ***Limitation 13B: "a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** As discussed above in Paragraphs 245-246, the '021 Publication discloses this limitation.

267. ***Limitation 13C: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall."*** As discussed above in Paragraphs 247-249, the '021 Publication in view of the knowledge of the POSA discloses this limitation.

268. ***Limitation 13D: "wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and."*** As discussed above in Paragraph 252, the '021 Publication discloses this limitation.

269. ***Limitation 13E: "wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture."*** I understand that Plaintiffs allege that a rail (specifically the rail to which the leg (378) in Defendants' ANDA Products mates) that extends to the lid/housing of the Defendants' ANDA Products is an inner wall cannister support formation that "extends from the main surface of the inner wall to the aperture." *See* Plaintiffs' Infringement Contentions to Cipla, Appendix 2 at 90. As discussed in Paragraph 252, above, the '021 Publication discloses an aperture formed in the inner wall through which the portion of the actuation member extends. As discussed in Paragraphs 247-250 above, it would have been obvious to place a rib or support formation adjacent to the actuation member. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). In such an arrangement the support formation would extend from the main surface of the inner wall to the cover in which the aperture is located, which according to Plaintiffs' allegations in the infringement contentions, satisfies this limitation. Accordingly, the '021 Publication in view of the knowledge of the POSA discloses this limitation. Thus, Claim 13 would have been obvious over the '021 Publication and the knowledge of the POSA.

270. Claim 14 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter."

As discussed above in Paragraph 251, the '021 Publication discloses this limitation. Thus, Claim 14 would have been obvious over the '021 Publication and the knowledge of the POSA.

271. Claim 15 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." As discussed above in Paragraph 253, the '021 Publication in view of the knowledge of the POSA discloses this limitation. Thus, Claim 15 would have been obvious over the '021 Publication and the knowledge of the POSA.

272. Claim 16 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon." As discussed above in Paragraph 254, the '021 Publication in view of the knowledge of the POSA discloses this limitation. Thus, Claim 16 would have been obvious over the '021 Publication and the knowledge of the POSA.

273. Claim 17 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body." As discussed above in Paragraph 255, the '021 Publication in view of the knowledge of the POSA discloses this limitation. Thus, Claim 17 would have been obvious over the '021 Publication and the knowledge of the POSA.

274. Claim 18 of the '587 Patent depends from Claim 17 and recites "the inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." As discussed above in Paragraph 256, the '021 Publication in view of the knowledge of the POSA discloses this limitation. Thus, Claim 18 would have been obvious over the '021 Publication and the knowledge of the POSA.

275. Claim 19 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body." As discussed above in Paragraph 257, the '021 Publication in view of the knowledge of the POSA discloses this limitation. Thus, Claim 19 would have been obvious over the '021 Publication and the knowledge of the POSA.

276. Claim 20 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture." As discussed above in Paragraph 269, the '021 Publication in view of the knowledge of the POSA discloses this limitation. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including tapered ribs for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Thus, Claim 20 would have been obvious over the '021 Publication and the knowledge of the POSA.

277. Claim 21 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port." A In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). As discussed above in Paragraph 250, the '021 Publication in view of the

knowledge of the POSA discloses this limitation. Thus, Claim 21 would have been obvious over the '021 Publication and the knowledge of the POSA.

278. Claim 22 of the '587 Patent depends from Claim 21 and recites "the inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X. As discussed above in Paragraph 262, the '021 Publication in view of the knowledge of the POSA discloses this limitation. Thus, Claim 22 would have been obvious over the '021 Publication and the knowledge of the POSA.

279. For at least these reasons, claims 1-8 and 11-22 of the '587 Patent would have been obvious over the '021 Publication and the knowledge of the POSA.

F. The Asserted Claims of the Common Plane Patents Would Have Been Obvious Over the '514 Publication in Combination with the '021 Publication

(i) *Claims 1-8 of the '289 Patent Would Have Been Obvious Over the '514 Publication in Combination with the '021 Publication*

280. In my opinion, claims 1-8 of the '289 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 over the '021 Publication in combination with the '514 Publication.

281. Claim 1 is the only independent claim of the '289 Patent. Claims 2-8 depend, either directly or indirectly from Claim 1. Claim 1 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

'289 Patent, claim 1.

282. Each limitation of Claim 1 would have been obvious over the '514 Publication in combination with the '021 Publication.

283. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** As discussed above in Paragraph 136, to the extent the preamble is limiting, the '514 Publication discloses this limitation.

284. ***Limitation 1A: "a main body having a canister housing."*** As discussed above in Paragraph 137, the '514 Publication discloses this limitation.

285. ***Limitation 1B: "a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and."*** As discussed above in Paragraph 138, the '514 Publication discloses this limitation.

286. ***Limitation 1C: "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** As discussed above in Paragraph 13-140, the '514 Publication discloses this limitation. As discussed above in Paragraph 246, the '021 Publication discloses a dose counter meeting this limitation for inclusion in known actuators, such as the '514 Publication.

287. ***Limitation 1D:*** **"wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and."** As discussed above in Paragraph 142, the '514 Publication discloses this limitation.

In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i).

288. ***Limitation 1E: "wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X."*** The actuator of the '514 Publication combined with the dose counter of the '021 Publication discloses this limitation. As discussed in Paragraphs 143-145, the '514 Publication discloses a canister housing with a longitudinal axis X passing through a central outlet port with inner wall canister support formations. As discussed in Paragraph 250, when the dose counter of the '021 Publication is incorporated into an actuator with ribs, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X. Accordingly, in my opinion, the combination of the actuator of the '514 Publication with the dose counter of the '021 Publication, discloses this limitation. Thus, Claim 1 would have been obvious over the '514 Publication in combination with the '021 Publication.

289. Claim 2 depends from claim 1 and recites, "the inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter." As discussed above in Paragraph 251, the '021 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '021 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 2 would have been obvious over the '514 Publication in combination with the '021 Publication.

290. Claim 3 depends from claim 1 and recites, "the inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." As discussed above in Paragraph 252, the '021 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '021 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 3 would have been obvious over the '514 Publication in combination with the '021 Publication.

291. Claim 4 of the '289 Patent depends from claim 1 and recites "the inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." As discussed above in Paragraph 147, the '514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '021 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 4 would have been obvious over the '514 Publication in combination with the '021 Publication.

292. Claim 5 of the '289 Patent depends from claim 4 and recites "the inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." As discussed above in Paragraph 149-150, the '514 Publication discloses this limitation. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Accordingly, the combination of the dose counter of the '021 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 5 would have been obvious over the '514 Publication in combination with the '021 Publication.

293. Claim 6 of the '289 Patent depends from claim 4 and recites "the inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." As discussed above in Paragraph 151, the '514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '021 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 6 would have been obvious over the '514 Publication in combination with the '021 Publication.

294. Claim 7 of the '289 Patent depends from claim 6 and recites "the inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." As discussed above in Paragraph 152-153, the '514 Publication discloses this limitation. Accordingly, the combination of the dose counter of the '021 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 7 would have been obvious over the '514 Publication in combination with the '021 Publication.

295. Claim 8 of the '289 Patent depends from claim 4 and recites "the inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." As discussed above in Paragraph 154-155, the '514 Publication discloses this limitation. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Accordingly, the combination of the dose counter of the '021 Publication and the actuator of the '514 Publication discloses this limitation. Thus, Claim 8 would have been obvious over the '514 Publication in combination with the '021 Publication.

296. For at least these reasons, claims 1-8 of the ’289 Patent would have been obvious over the ’514 Publication in combination with the ’021 Publication.

(ii) *Claims 1-8 and 11-22 of the ’587 Patent Would Have Been Obvious Over the ’514 Publication in Combination with the ’021 Publication*

297. In my opinion, claims 1-8 and 11-22 of the ’587 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the ’514 Publication in combination with the ’021 Publication.

298. Because claims 1-8 and 12 of the ’587 Patent are essentially identical to claims 1-8 of the ’289 Patent, they would have been obvious over the ’514 Publication in combination with the ’021 Publication for the same reasons set forth in Section XV.F.(i)., above.

299. In addition, even if reciting the purpose added an element to the claims, the ’021 Publication in combination with the ’514 Publication discloses the purpose recited in claims 1 and 12. As discussed above, the ’021 Publication in combination with the ’514 Publication discloses every structural element of claims 1 and 12, therefore the inhaler and dose counter disclosed therein would inherently perform the recited purpose, thereby rendering obvious claims 1-8 and 12 of the ’587 Patent.

300. Claim 11 of the ’587 Patent depends from claim 1 and recites “the inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.” As discussed in Paragraphs 137-145 and 152-153, above, in connection with claims 1 and 7 of the ’289 Patent, the ’514 Publication discloses an actuator with a second inner wall canister support formation and a diametrically opposed first inner wall canister support formation. As discussed in Paragraph 288, above, in connection with claim 1 of the ’289 Patent,

the combination of the dose counter from the '021 Publication and the actuator of the '514 Publication discloses the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X. Because the inner wall canister support formations of the '514 Publication are evenly spaced, and therefore direct opposites, the second inner wall canister support formation would also lie in the common plane coincident with longitudinal axis X. In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the '514 Publication for use with the dose counter of the '021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). Accordingly, the actuator of the '514 Publication in combination with the dose counter of the '021 Publication renders this claim obvious. Thus, Claim 11 would have been obvious over the '514 Publication in combination with the '021 Publication.

301. Claim 13 recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

'587 Patent, claim 13.

302. ***Preamble: "An inhaler for metered dose inhalation, the inhaler comprising."*** As discussed above in Paragraph 136, to the extent the preamble is limiting, the '514 Publication discloses this limitation.

303. ***Limitation 13A: "a main body having a canister housing."*** As discussed above in Paragraph 137, the '514 Publication discloses this limitation.

304. ***Limitation 13B: "a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."*** As discussed above in Paragraphs 138-140, the '514 Publication in combination with the '021 Publication discloses this limitation.

305. ***Limitation 13C: "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall."*** As discussed above in Paragraph 142, the '514 Publication discloses this limitation.

306. ***Limitation 13D: "wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and."*** As discussed above in Paragraph 252, the '021 Publication discloses this limitation.

307. ***Limitation 13E: "wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture."*** As discussed above in Paragraph 269, the combination of the '514 Publication and '021 Publication discloses this limitation. Thus, Claim 13 would have been obvious over the '514 Publication in combination with the '021 Publication.

308. Claim 14 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter." As discussed above in Paragraphs 251 and 289, the combination of the '514 Publication and '021 Publication discloses this limitation. Thus, Claim 14 would have been obvious over the '514 Publication in combination with the '021 Publication.

309. Claim 15 of the '587 Patent depends from Claim 13 and recites "the inhaler as claimed in claim 13, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." As discussed above in Paragraph 291, the '514 Publication discloses this limitation. Thus, Claim 15 would have been obvious over the '514 Publication in combination with the '021 Publication.

310. Claim 16 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon." As discussed above in Paragraph 292, the '514 Publication discloses this limitation. Thus, Claim 16 would have been obvious over the '514 Publication in combination with the '021 Publication.

311. Claim 17 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body." As discussed above in Paragraph 293, the '514 Publication discloses this limitation. Thus, Claim 17 would have been obvious over the '514 Publication in combination with the '021 Publication.

312. Claim 18 of the '587 Patent depends from Claim 17 and recites "the inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." As discussed above in Paragraph 294, the '514 Publication discloses this limitation. Thus, Claim 18 would have been obvious over the '514 Publication in combination with the '021 Publication.

313. Claim 19 of the '587 Patent depends from Claim 15 and recites "the inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body." As discussed above in

Paragraph 295, the ’514 Publication discloses this limitation. Thus, Claim 19 would have been obvious over the ’514 Publication in combination with the ’021 Publication.

314. Claim 20 of the ’587 Patent depends from Claim 15 and recites “the inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the ’514 Publication for use with the dose counter of the ’021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). As discussed above in Paragraph 307, the combination of the ’021 Publication and ’514 Publication discloses this limitation. Thus, Claim 20 would have been obvious over the ’514 Publication in combination with the ’021 Publication.

315. Claim 21 of the ’587 Patent depends from Claim 13 and recites “the inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port.” In my opinion, a person of skill in the art would have been motivated to modify or select such an actuator including ribs, such as the one disclosed in the ’514 Publication for use with the dose counter of the ’021 Publication, and expected success in doing so, for the same reasons discussed in Section XV.C.(i). As discussed above in Paragraph 288, the combination of the ’021 Publication and ’514 Publication discloses this limitation. Thus, Claim 21 would have been obvious over the ’514 Publication in combination with the ’021 Publication.

316. Claim 22 of the ’587 Patent depends from Claim 21 and recites “the inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X. As discussed above in Paragraph 300, the combination of the ’021 Publication and ’514 Publication discloses this limitation. Thus, Claim 22 would have been obvious over the ’514 Publication in combination with the ’021 Publication.

317. For at least these reasons, claims 1-8 and 11-22 of the ’587 Patent would have been obvious over the ’514 Publication in combination with the ’021 Publication.

XVI. INVALIDITY OF THE ’156 PATENT

318. The ’156 Patent is directed to a dose counter for MDI inhalers where the parts of the dose counter move through a series of specified positions during a firing sequence. The ’156 Patent claims a dose counter that, in the fire configuration, the actuator pawl of the dose counter is below a datum plane, which passes through a shoulder of a valve stem block. *See* ’156 Patent, Claim 1.

319. The valve stem block 40 is described as the structure in which the valve stem 38 of the inhaler is “sealingly engaged.” ’156 Patent at 12:25-31. The structures are shown in Figure 7A below:

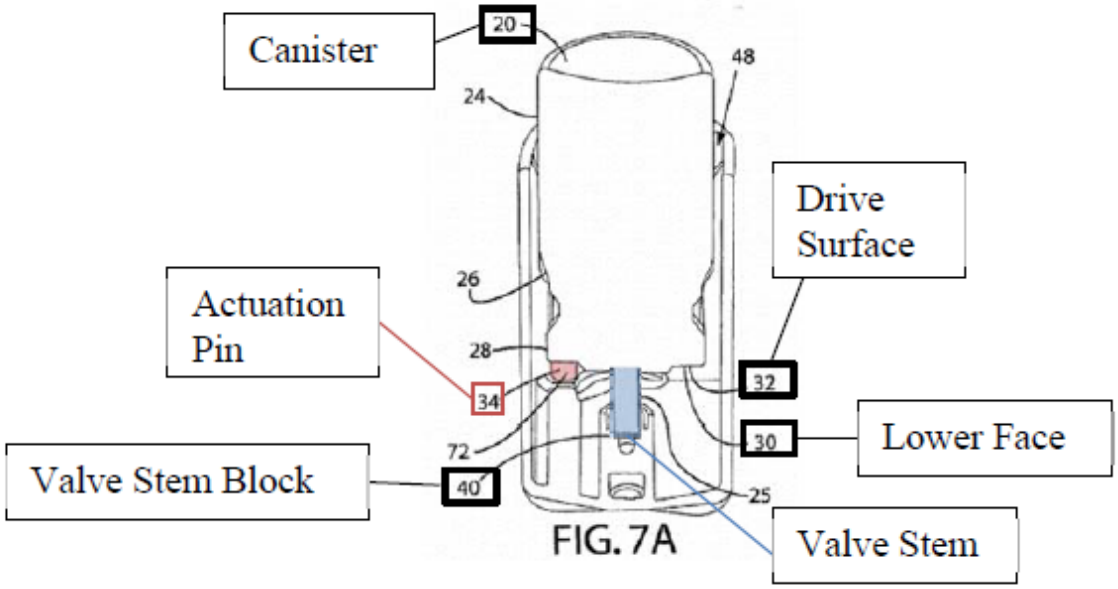


FIG. 7A

320. The '156 Patent depicts a close-up image of the valve stem block, showing the datum plane, as Figure 9, reproduced with annotations below:

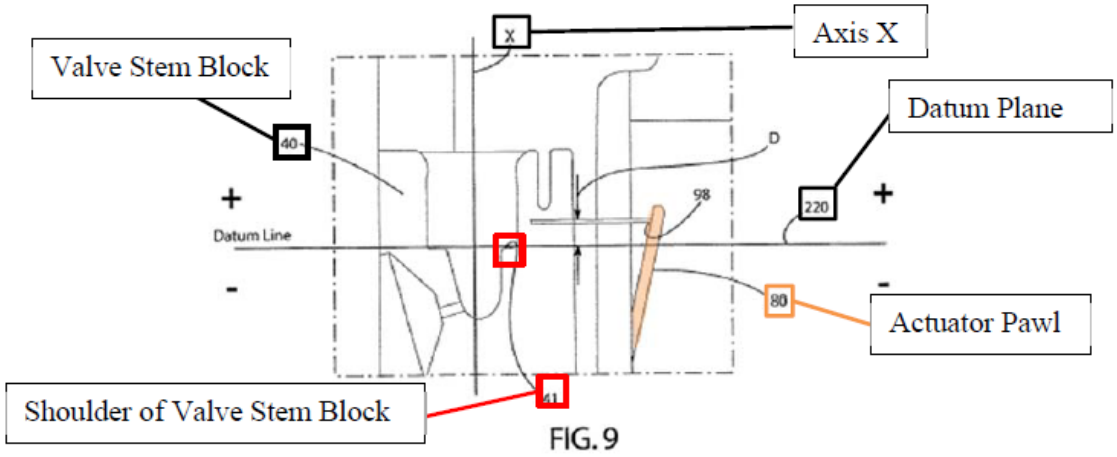


FIG. 9

321. Figure 9 depicts the dose counter in the "start" configuration, where the actuator pawl is above the datum plane. *Id*. at 14:11-26. The '156 Patent explains that as the canister is depressed, this causes the actuation pin 34, and correspondingly the actuation pawl 80, to move downward so that the actuator pawl 80 is below the datum plane. *Id*. at 14:50-61 ("The configuration shown in Fig. 10D is known as the 'Fire' configuration. In this configuration, the

lower side edge 98 of the actuation 80 is 0.47 mm below the datum plane 220."). The datum plane limitation was the basis on which the claims of the '156 Patent were allowed, following three years of prosecution. *See* '156 Patent Prosecution History, May 31, 2018 Notice of Allowance at 2.

322. In addition to requiring the actuator pawl to be in a certain location relative to the datum plane when in the fire configuration, the '156 Patent recites several other positions that occur during the firing sequence, including "a first reset position," "a canister fire configuration," and "a count configuration." The '156 Patent describes the fire sequences positions as follows: Prior to the user pressing down on the canister engage the actuation member, the canister is in a "start position." *See* '289 Patent at 14:15-15. In this position, a count pawl 138 engages with a tooth of a ratchet wheel, while the actuator pawl is spaced therefrom. *See* '156 Patent at 14:16-18, 14:47, Fig. 10B. Figure 10B, annotated with a red circle to indicate the actuator pawl and a green circle to indicate the count pawl, shows the "start configuration."

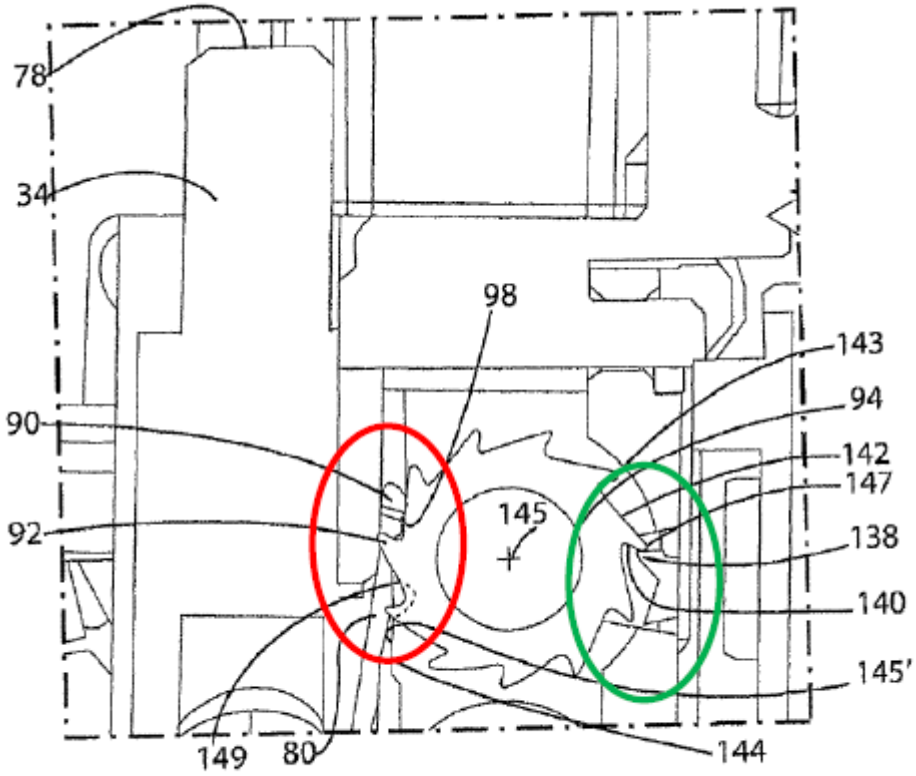


FIG. 10B

323. When the user presses down on the canister to "fire" the inhaler, the actuator pawl is moved downwards until it engaged with one of the teeth of the ratchet wheel (145). This position is identified by the '156 Patent as the "first reset position," and is shown below in Figure 10C. *See* '156 Patent at 14:42-49, Fig. 10C.

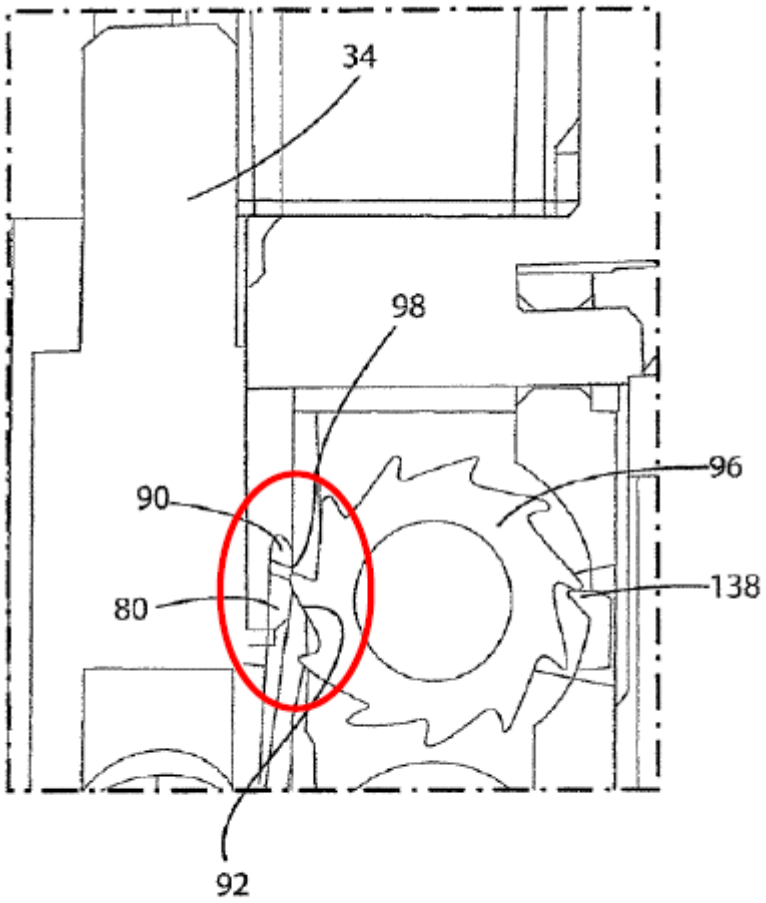


FIG. 10C

324. The '156 Patent discloses that, as the user continues to press the canister down, the actuation pawl continues to lower and rotates the ratchet wheel until the inhaler ejects medicament and propellant. *See id.* at 14:50-61. The point at which the medicament and propellant is ejected is termed the "fire configuration." *Id.* At this point, as shown in figure 10D, the actuator pawl is below the datum plane line.

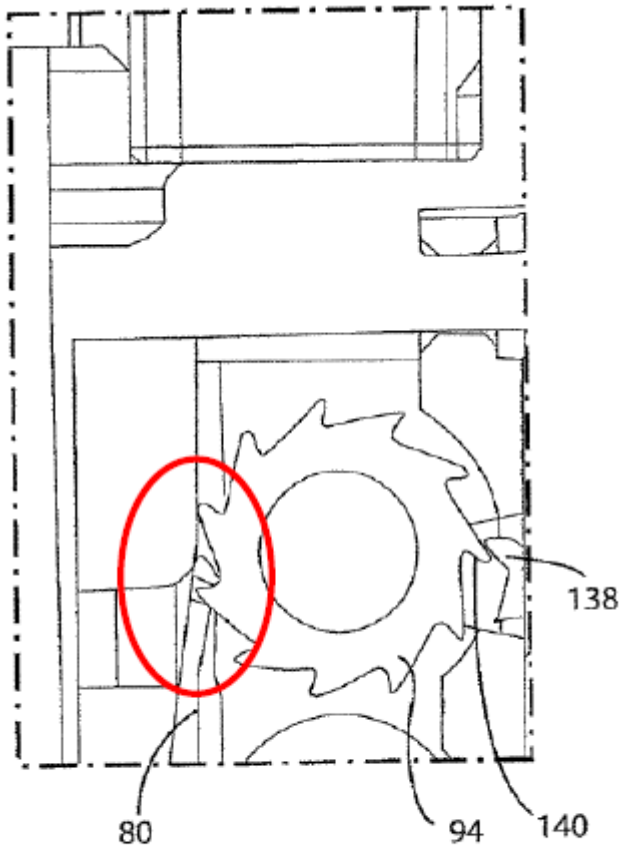


FIG. 10D

325. I understand that the Parties have disputed the constructions of "canister fire sequence," "first reset position," "canister fire configuration," and "count configuration." I have reviewed both constructions and determined that Plaintiffs' construction encompasses Defendants' proposed construction for each term. Accordingly, I have applied Defendants' proposed construction with the understanding that if the prior art discloses the limitation when construed using Defendants' construction, the limitation construed using Plaintiffs' construction is necessarily met.

326. I understand that Plaintiffs are asserting claims 1-2, 9, and 11-13 of the '156 Patent.

327. Claim 1 is the only independent claim of the '156 Patent. Claims 2, 9, and 11-12 depend, either directly or indirectly, from Claim 1. Claim 1 recites:

> A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
>
> A ratchet wheel having a plurality of circumferentially spaced teeth,
>
> an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
>
> a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,
>
> a dosage indicator associated with the count pawl,
>
> wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
>
> wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,
>
> wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

328. As discussed in detail below, in my opinion, each asserted claim of the '156 Patent is invalid in view of the prior art.

A. Claims 1, 9, and 11-13 of the '156 Patent are Anticipated by the '021 Publication

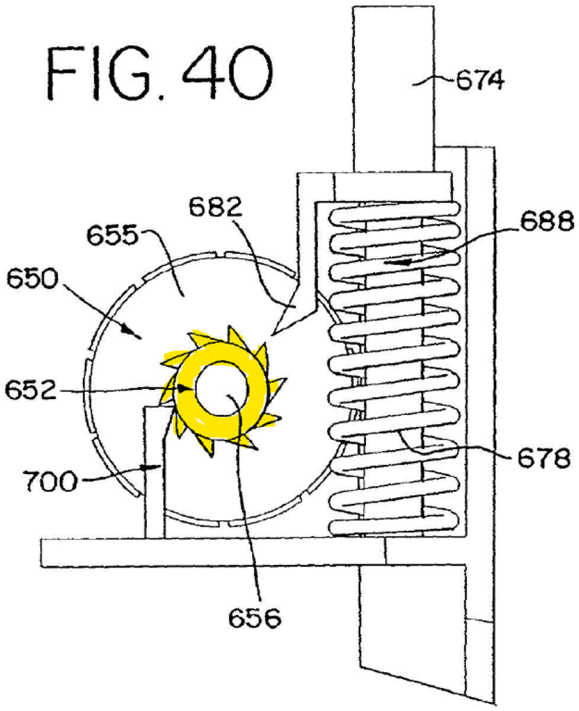
329. In my opinion, claims 1, 9, and 11-13 of the '156 Patent are invalid at least because they are anticipated under 35 U.S.C § 102(b) by the '021 Publication.

330. ***Preamble: "A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising."*** To the extent the preamble is limiting, the '021 Publication discloses

this limitation. *See* '021 Publication at Abstract ("An indicating device for use with a dispensing device that dispenses metered doses of medicament from a container having a valve moveable between an open and closeable position. . . . the container is reciprocally moveable within the housing."); ¶ [0002] ("The present invention relates generally to an indicating device, and in particular, to an indicating device for indicating the number of metered dosages of a substance, and in particular a medicament, that have been dispensed by, or remain in, a dispensing device."); ¶ [0076] ("The container 100 is formed as a cylindrical canister 104. . . .It should be understood that the container can be configured in a variety of shapes and sizes, and that the substance contained therein can be released by any number of valve systems that are well known in the art."); ¶ [0088] ("In the operation of the embodiment shown in FIGS. 6-9, 13-18 and 20, the container is moved longitudinally within the housing so as to depress the valve stem to the open position so as to open the valve as explained above. As the container is moved downwardly within the housing, the actuator member 70 is moved longitudinally downward such that the hook member 82 engages the ratchet wheel and rotates it a predetermined angular amount corresponding to the pitch of the teeth. When the container is released by the user, the spring (not shown) within the container biases the container upwardly within the housing along the longitudinal axis such that the valve stem 110 is moved to the closed position within the container so as to close the valve."); Fig. 6; Fig. 8.

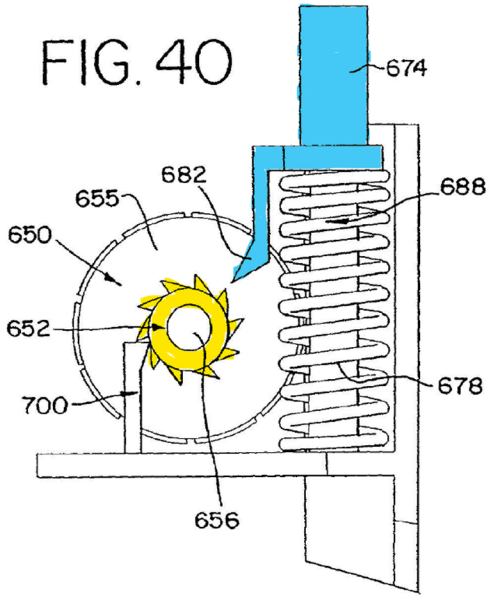
331. ***Limitation 1A: "a ratchet wheel having a plurality of circumferentially spaced teeth."*** The '021 Publication discloses a ratchet wheel. *See, e.g., id.* at ¶ [0101] ("Referring to Figs. 25 and 39, an actuator member 570, 670, otherwise referred to as a ratchet member, is shown as having an upper portion 574, 674 extending upwardly from a lower portion 578, 682 and a resilient arm member 580, 680 extending outwardly therefrom and terminating in a resilient hook member 582, 682 shaped to selectively engage at least one of the teeth of the ratchet gear of the

first indicator member."). The ratchet wheel 32 (yellow) is shown below in Figure 40 (another view of embodiment 39) and the circumferentially spaced teeth are plainly visible:



332. ***Limitation 1B: "an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate."*** The '021 Patent discloses this limitation. The '021 Publication discloses an actuator 674 with resilient arm 680 and tapered hook member 682 "shaped to selectively engage at least one of the ratchet wheel teeth." *Id*. at ¶ [0101]. In use, "the container is moved longitudinally within the housing so as to depress the valve stem to the open position so as to open the valve as explained above. As the container is moved downwardly within the housing, the actuator member 70 [(674 in the embodiment of Fig. 40)] is moved longitudinally downward such that ***the hook member 82 [(682)] engages the ratchet wheel*** and rotates it a predetermined angular amount corresponding to the pitch of the teeth." *Id*. at ¶ [0088] (emphasis added); *see also id*. at [0104] ("The operation of the actuator member 670 and ratchet gear is similar to the operation

of the ratchet gear shown in Figs. 6-9, as explained above"). The actuator, including the arm and hook, (blue) and ratchet wheel (yellow) are depicted below in Figure 40:

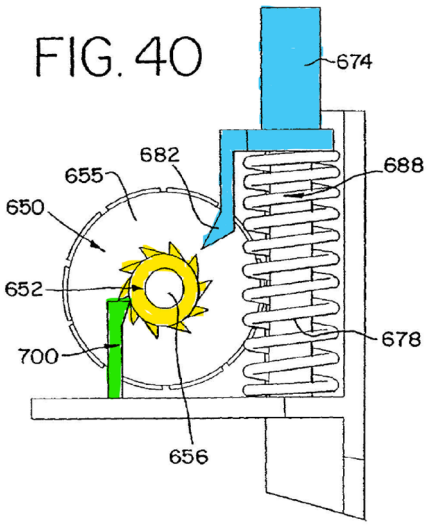


333. ***Limitation 1C: "a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth."*** The '021 Patent discloses a count pawl, engaged with a second tooth of the ratchet wheel. *See id.* at ¶ [0104] ("Referring to FIGS. 39-41 and 44-48, a plurality of resilient arm members 700 are shown as extending from a module housing so as to be aligned with the ratchet gears on each of the indicator members. The arm members 700 each serve as a combined engagement member and non-return member. In particular, as shown in FIGS. 40 and 41, the arm member 700 functions as a non-return member and includes an end portion that is biased away from the teeth on the ratchet gear as the actuator member, or adjacent indicator member with its advancement member, is actuated to advance the ratchet gear. The operation of the actuator member 670 and ratchet gear is similar to the operation of the ratchet gear shown in FIGS. 6-9 as explained above."); *see also id.* ¶ [0091] ("a resilient non-return member 200 engages the ratchet gear adjacent the hook member

so as to ensure that the rotation of the ratchet gear is unidirectional. Alternatively, the non-return member can be positioned to engage the ratchet gear opposite the actuator arm member.").

334. In addition, the '021 Patent discloses that the count pawl rides along a forward surface of a second tooth and resiliently jumps over the second tooth. *See id.* at [0104] ("The arm member 700 snaps back so that the end portion engages one of the teeth of the ratchet gear so as to ensure that the rotation of the ratchet gear is unidirectional. As shown in FIGS. 44-47, the arm member 700 overlying the ratchet gears of the second and third indicator members also serves as an engagement member that selectively engages the advancement members connected to the indicator members."); *see also id.* at [0091] ("The non-return member includes an end portion adapted to engage the engagement surface of the ratchet gear teeth. As the ratchet gear is rotated by the actuator, the non-return member slides along the tapered surface of one of the teeth of the ratchet wheel and does not interfere with the rotation thereof.").

335. The count pawl (actuation member 700) is shown in Figure 40 below in green:



336. ***Limitation 1D: "a dosage indicator associated with the count pawl."*** The '021 Patent discloses this limitation. As discussed above, the '021 Publication discloses a count pawl, that prevents backwards rotation of the ratchet wheel and "serves as an engagement member that

selectively engages the advancement members connected to the indicator members." Thus, the dosage indicator is disclosed to be associated with the count pawl (arm member 700).

337. ***Limitation 1E: "wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth."*** In use, the dose counter disclosed in the '021 Publication passes through a first reset position. As can be seen in Figure 40, in the rest position (e.g., before the actuator has been depressed) the actuator pawl (hook 682) has not yet engaged with a first tooth of the ratchet wheel. Once the actuator has been compressed (e.g., a full stroke), the actuator pawl must connect with the ratchet wheel in order to begin rotating it, as explained in Paragraph 332, above. *See also* '021 Publication at ¶¶ [0101], [0088]. Thus, the actuator pawl of the dose counter disclosed in the '021 Publication will necessarily pass through a first reset position in which the actuator pawl is brought into engagement with the first tooth of a ratchet wheel.

338. I understand that the Parties have proposed different constructions for "first reset position." I understand that the primary difference in these constructions is that Defendants' construction indicates that, in the first reset position, the actuator pawl is above the datum plane line," while Plaintiffs' construction is silent as to this locational requirement. In my opinion, the '021 Publication discloses that the actuator pawl is above the datum plane line when in the first reset position. As discussed below, the datum plane line (under either Party's construction) should be drawn at the top of orifice 20. When drawn at this point, as shown in Figure 7 below, the datum plane line passes through the center of the valve stem. I apply this same datum plane to Figures 48 and 40 below.

FIG. 48

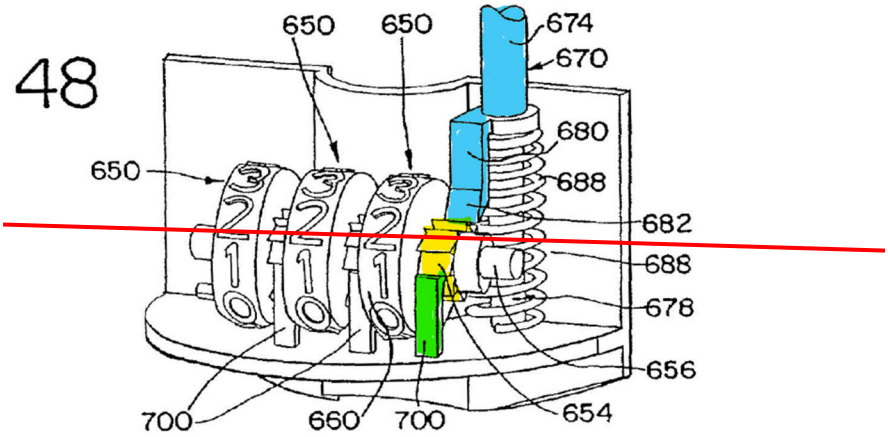
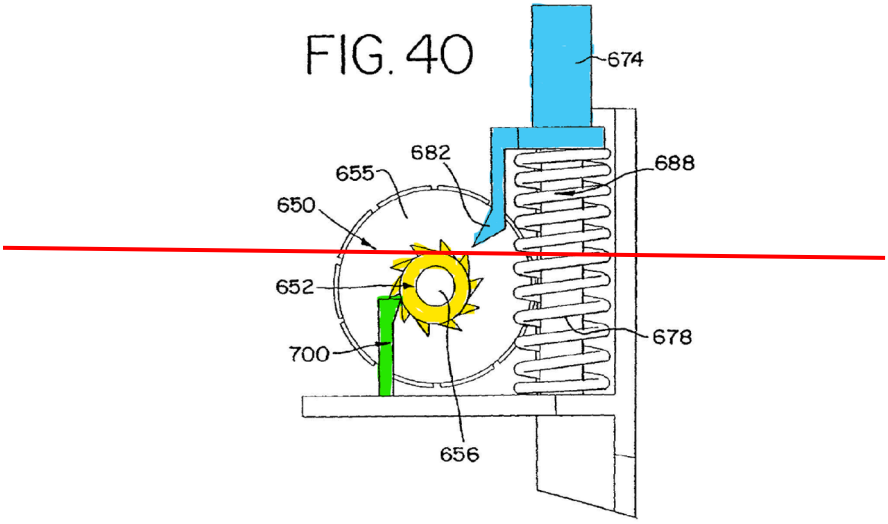


FIG. 40



339. As can be seen in Figures 40 and 48, in the actuator pawl is above the datum plane, when just in connection with the ratchet wheel (i.e., in the first reset position under Defendants' proposed construction). Accordingly, because this limitation is disclosed under even Defendants' construction, my opinion remains the same irrespective of which construction is applied.

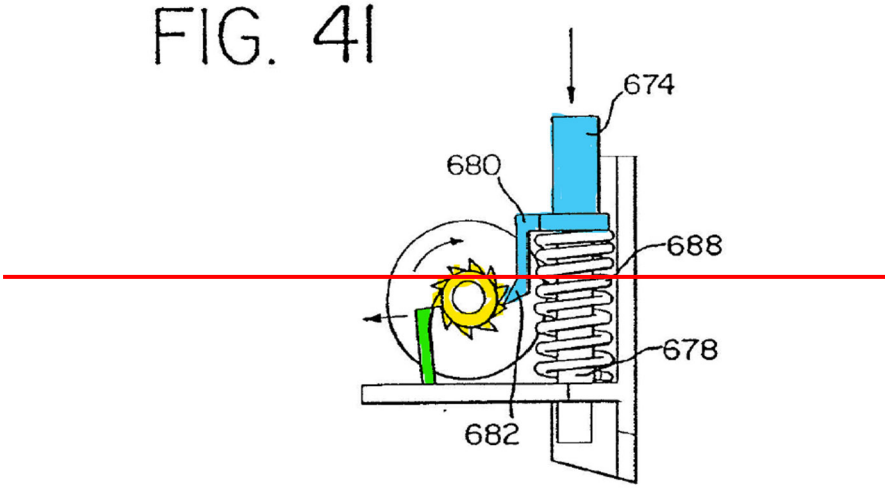
340. ***Limitation 1F: "wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position***

after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count." In my opinion, the '021 Publication discloses that the actuator pawl is below the datum plane line when in the canister fire configuration. As discussed above, the downward movement of the canister moves the actuator pawl downwards to rotate the ratchet wheel clockwise until the count pawl jumps over the second tooth, at which point a count is indicated. *See* Paragraphs 332 and 337. This full stroke has occurred at or just after the time the canister fires (e.g., is in the canister fire configuration).

341. I understand that the Parties have proposed different constructions for "canister fire configuration." I understand that the primary difference in these constructions is that Defendants' construction indicates that, in the canister fire configuration, the actuator pawl is below the datum plane line," while Plaintiffs' construction is silent as to this locational requirement.

342. Figure 41 depicts the dose counter disclosed in the '021 Publication in the fire configuration, during a downward stroke, just before a count has been indicated (as evidenced by the fact that the count pawl is just about to jump over the second tooth of the ratchet wheel). In this position, the actuator pawl is already below the datum plane line, confirming that in the fire configuration, it will also be below the datum plane.

FIG. 41

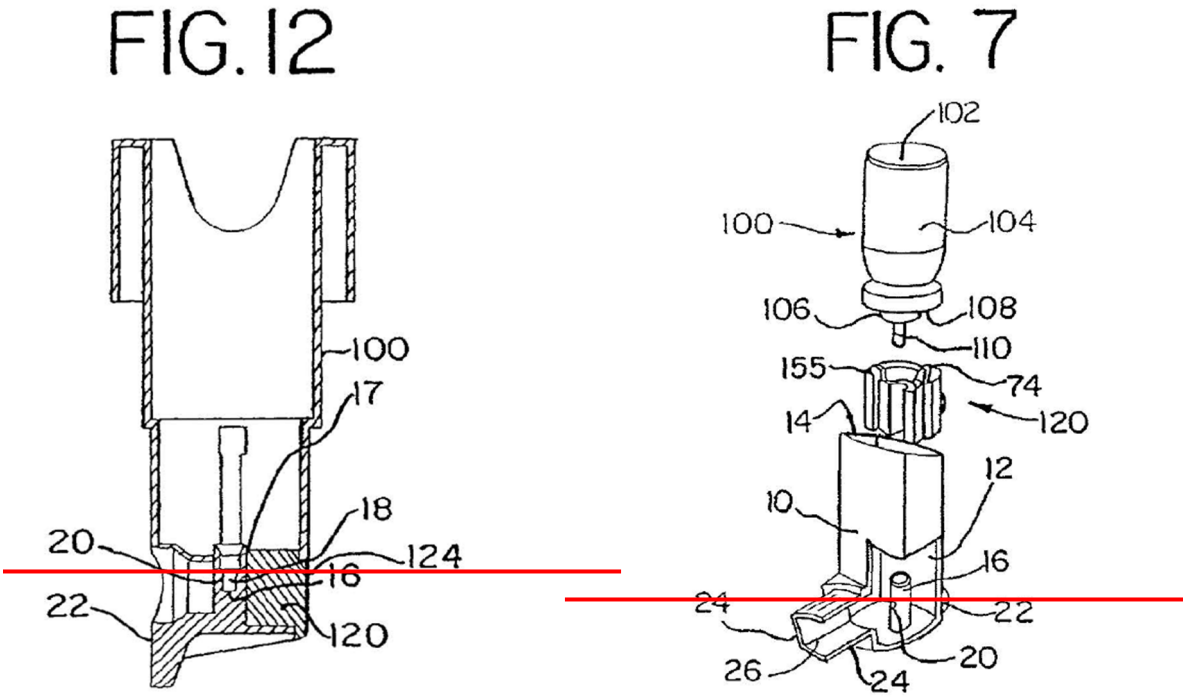


343. I also understand that the Parties have proposed different constructions of "canister fire sequence." I understand that the primary difference between these constructions is that Defendants' proposed construction requires that, in the rest or start configuration, the count pawl is engaged with a tooth of the ratchet wheel, while the actuator pawl is spaced from the ratchet wheel. As shown in Figure 40 above, in the start position, the '021 Publication discloses that the count pawl is engaged with a tooth of the ratchet wheel, while the actuator pawl is spaced from the ratchet wheel.

344. Accordingly, because this limitation is disclosed under even Defendants' constructions of disputed terms, my opinion remains the same irrespective of which construction is applied.

345. ***Limitation 1G: "wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister."*** I understand that the Parties have proposed different constructions for the phase "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." Figure 7 of the '021 Publication discloses how the dose counter chamber 120 can be inserted into a canister housing. Figure 12 shows the interior

of the valve stem. In Figures 12 and 7, orifice 20 depicts where medicament is expelled from the valve stem. Thus, under either Party's construction, the datum plane line must be placed at this orifice, as no other potential "shoulder" structure, exists. *See* Fig. 12. I have drawn this datum plane line in red in Figures 12 and 7.



346.

347. For all of these reasons, claim 1 of the '156 Patent is anticipated by the '021 Publication.

348. Claim 9 depends from claim 1 of the '156 Patent and recites "A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween." The '021 Publication discloses that the actuator pawl and count pawl are arranged to permit one way incremental movement. *See id.* at [0104] ("The arm member 700 snaps back so that the end portion engages one of the teeth of the ratchet gear so as to ensure that the rotation of the ratchet gear is unidirectional."). Accordingly, this limitation is disclosed by the '021 Publication. Thus, Claim 9 is anticipated by the '021 Publication.

349. Claim 11 depends from claim 1 and recites, "[a]n inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1." The '021 Publication discloses this limitation. For example, it discloses the use of a medicament canister in the body, along with a dose counter. *See e.g.*, Figs. 1-7, 10, 21, 24. Thus, Claim 11 is anticipated by the '021 Publication.

350. Claim 12 depends from Claim 11 and recites, "[a]n inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator."

351. For the reasons discussed in detail in Section XVI.D, below, this claim is structurally impossible and indefinite.

352. I understand that Plaintiffs have proposed a construction rewriting this claim in an attempt to preserve validity, whereby "the body," when used the second time only, refers to "the dose counter body." If the claim is found definite and Plaintiffs' construction is adopted, the '021 Publication discloses this limitation. The '021 Publication discloses that the indicator assembly is arranged in an indicator module 120, 1020, 1120. *See id*. at [0108]. The indicator module, or counter chamber, contains the "body of the dose counter," the ratchet wheel and the actuator. *See* Figs. 6, 7, 8, 9, 11, 39. In addition, as shown in Figs. 6 and 39, actuator member 74, 674, extends through an aperture in the module 1156, in order to receive motion transmitted from the canister. *See* Figs. 6, 39.

353. Although the claim requires that the body of the inhaler has wall surfaces separating the canister-receiving portion and the counter chamber, and that these wall surfaces include the aperture through which the actuator member extends, I understand that Plaintiffs have contended that the lid of the housing in Defendants' ANDA Products, which housing is a separate and removable chamber in which the dose counter is located, still literally meets this limitation, or is equivalent to wall surfaces separating the canister-receiving portion and the counter chamber. *See* Plaintiffs' Infringement Contentions to Cipla at Appendix 3 at 58-61. Thus, the disclosure of a separate chamber with a lid including an aperture, as disclosed by the '021 Publication discloses this limitation.

354. I understand the Parties have proposed different constructions for "separate counter chamber." I understand the primary difference between the two constructions is that Defendants' proposed construction requires the chamber be formed by the inner walls of the body of the inhaler, while Plaintiffs' proposed construction merely requires a separate chamber. This limitation is met under Plaintiffs' construction for the reasons set forth above. In addition, to the extent that Defendants' proposed construction is adopted, and Plaintiffs contend that a separate chamber not comprised of the inner walls of the body (as seen in Defendants' ANDA Products) meets this claim under the doctrine of equivalents, then the separate dose counter chamber disclosed in the '021 Publication also anticipates this claim under Defendants' proposed construction.

355. Claim 13 depends from claim 1 and recites "The dose counter of claim 1, wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister." When drawn in accordance with either Party's construction, the datum plane line disclosed in the '021 Publication is represented by the red lines in Figures 7, 12, 40, 41, and 48, as discussed above.

356. As also discussed above, in use, the canister is moved by the user depressing it, in other words, pressing downwards. Thus, the datum plane line is perpendicular to the movement of the canister. In addition, as can be seen in Figure 12, above, the datum plane line is the bottom surface of the valve stem block. Thus, Claim 13 is anticipated by the '021 Publication.

B. Claims 1-2, 9, and 11-13 Would Have Been Obvious Over the '552 Publication

357. In my opinion, claims 1-2, 9, and 11-13 of the '156 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '552 Publication, in combination with the knowledge of a person of ordinary skill in the art.

358. ***Preamble: "A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising."*** To the extent the preamble is limiting, the '552 Publication discloses this limitation. *See* '552 Publication at Abstract ("the present invention relates to a metered inhaler dose counter"); 1:15-18 ("Such metered-dose inhalers typically include a medicament-containing vessel"); 1:20-21 ("The medicament-containing vessel may be a pressurized canister containing a mixture of active drug and propellent"); 3:26-30 ("Actuation of the metering-valve assembly is effected by causing downward movement of the aerosol canister 6 relative to the actuator body 2.").

359. ***Limitation 1A: "a ratchet wheel having a plurality of circumferentially spaced teeth."*** The '552 Publication discloses "a wheel 30 mounted on a spindle (not shown), the wheel 30 having a plurality of ratchet teeth 32 around its periphery." *See id*. at 8:10-17. This wheel (yellow), with a driver (or actuator pawl) 28 (blue) is shown in Figure 5, below:

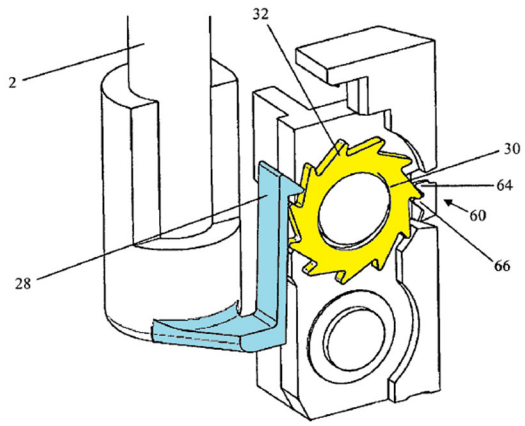


Fig. 5

360. ***Limitation 1B: "an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate."*** The '552 Publication discloses this limitation. In particular, it discloses "an actuator 20" along with "a driver 28 for driving the rotary gear in a step-wise fashion in response to the actuator 20." *See id.* at 8:10-17. As can be seen in Figure 5, above, driver 29, shown in blue, is an actuator pawl, and it is engaged with a first tooth of a ratchet wheel 30, shown in yellow. The '552 Publication further explains that, in use, the "user depresses the aerosol canister 6 which causes displacement of actuator 20 . . . In the embodiment shown in Fig. 5, the movement of the rotary gear [(i.e., ratchet wheel 30)] occurs during displacement of the actuator from the first position to the second position." *Id*. at 9:21-31. As can be seen in Figure 5 below, the actuator (mislabeled 2, rather than 20, in the image) is shown in light purple. The actuator has a boss, shown in green, formed at its base. Driver 28 (actuator pawl shown in blue) is integrally molded with the boss. *See id*. at 4:5-6, 4:12-13, and 8:7:8.

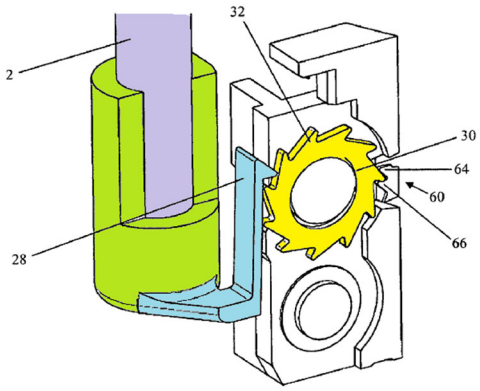


Fig. 5

361. ***Limitation 1C: "a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth."*** The '552 Publication discloses a count pawl 60. As can be seen in Figure 5, shown in red, the count pawl engages with a second tooth of the ratchet wheel.

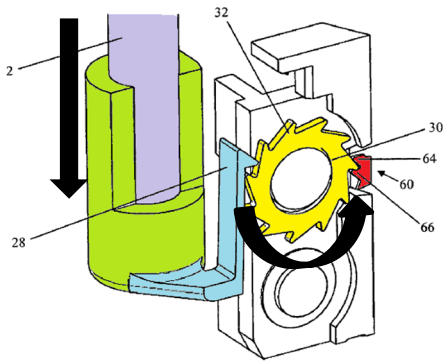


Fig. 5

362. As shown with arrows in the above figure, when the canister is depressed during use, the actuator (purple) is pressed downwards, this movement causes the actuator pawl (blue) to move downwards. As the actuator pawl (blue) is moved the hook, engaged with a first tooth of the ratchet wheel (yellow), moves downward and rotates the wheel in a counterclockwise direction. As the wheel moves, the count pawl 60 "radially outwardly deforms to allow the wheel 30 to rotate

by one tooth 32. The at least two teeth 64, 66 of pawl 60 may be inherently resilient to allow the required radially outward deformation and return." *Id*. at 10:10-12. In other words, as the wheel rotates, the count pawl rides along the forward surface of the second tooth, and resiliently jumps over the second tooth. *See id*. at 12:11-19. This is also shown in Figures 8a and 8b, which depict the count pawl 30 before and after it has ridden along the front surface of the second tooth (orange) and resiliently jumped over that tooth:

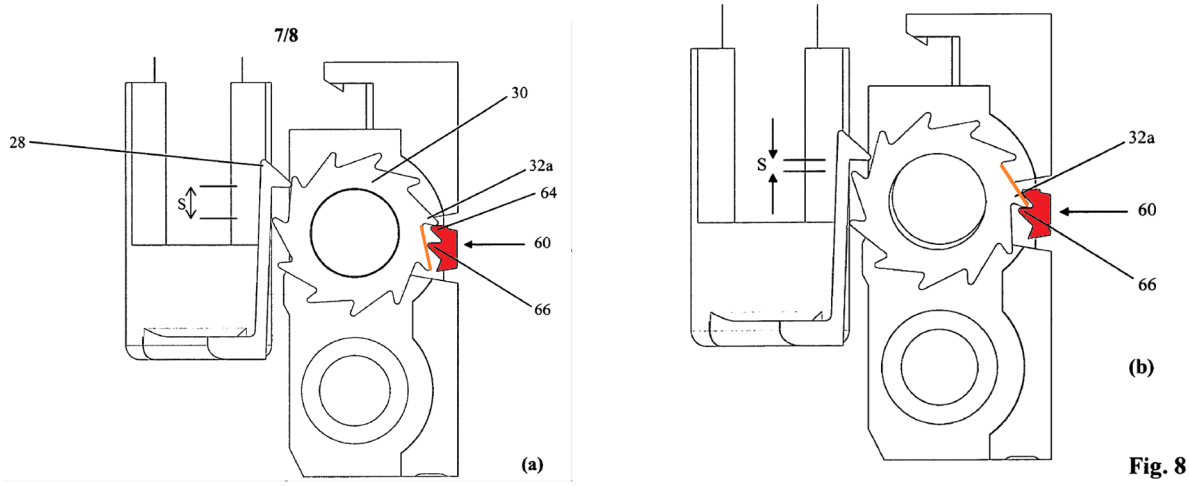


Fig. 8

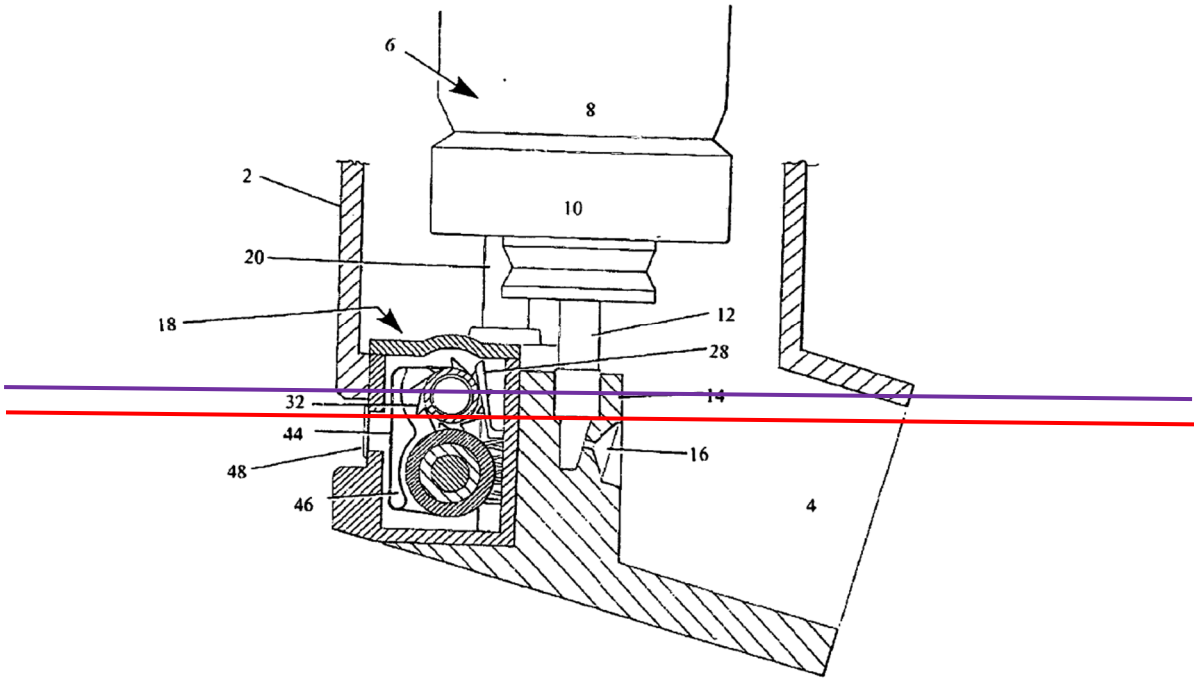
363. ***Limitation 1D: "a dosage indicator associated with the count pawl."*** The '552 Publication also discloses this limitation, explaining that "[t]he [count] pawl 60 radially outwardly deforms to allow the wheel 30 to rotate by one tooth 32." *Id*. at 10:10. The '552 Publication further explains that the dose counter of the invention includes a "display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step-wise rotary motion of the rotary gear [(i.e., ratchet wheel)]." *Id*. at 8:15-17.

364. ***Limitation 1E: "wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth."*** In use, the dose counter disclosed in the '552 Publication passes through a first reset position. As can be seen in Figure 8a, above, in the rest position the actuator pawl is not yet engaged with a first tooth. As

shown in Figure 8b, once the plunger is compressed the actuator pawl is in connection with the first tooth in order to rotate the ratchet wheel. *See also id.* at 8:10-17, 9:21-31. In order to perform its intended function, it must pass through a position in which the actuator pawl is brought into engagement with the first tooth.

365. I understand that the Parties have proposed different constructions for "first reset position." I understand that the primary difference in these constructions is that Defendants' construction indicates that, in the first reset position, the actuator pawl is above the datum plane line," while Plaintiffs' construction is silent as to this locational requirement. In my opinion, the '552 Publication discloses that the actuator pawl is above the datum plane line when in the first reset position.

366. The '552 Publication makes clear that the invention is essentially the same as the prior art except that the count pawl 60 has been changed. *See* id. at 8:7-8. The prior art embodiments which the '552 Publication improved upon disclose that, in the start or rest position, the actuator pawl is above the datum plane (shown with a red line). Based on the rotation distance, when the actuator pawl is brought into engagement with the first tooth (shown with a purple line), but has not yet begun rotating it (e.g., in the first reset position), it is still above the datum plane line.



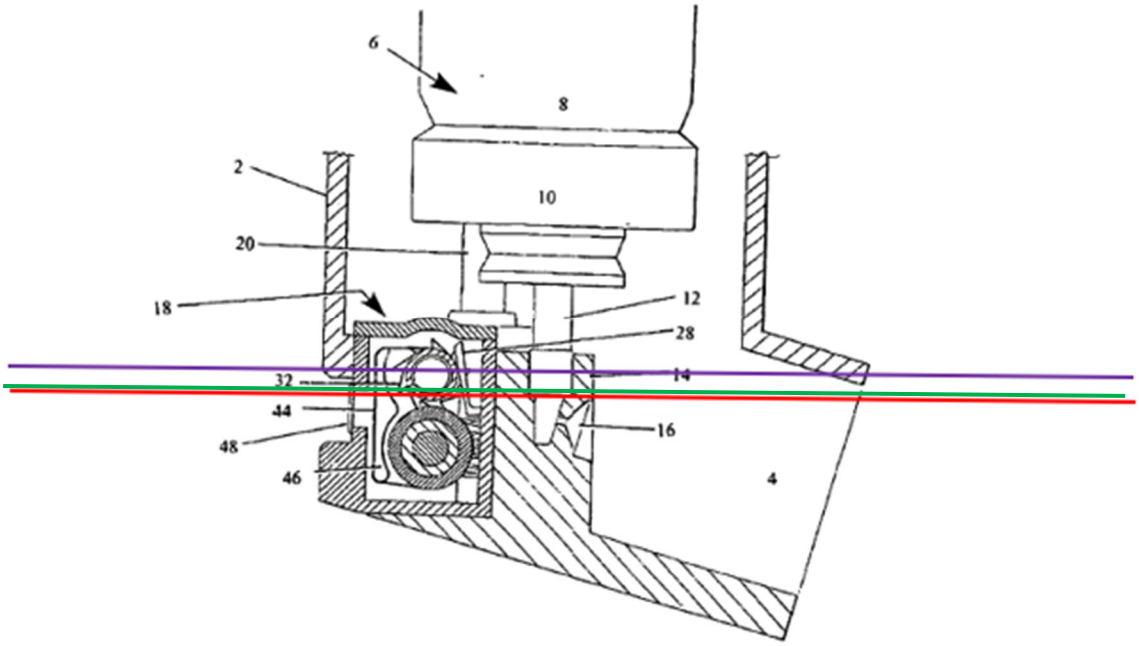
367. Accordingly, because this limitation is disclosed under even Defendants' construction, my opinion remains the same irrespective of which construction is applied.

368. ***Limitation 1F: "wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count."*** As discussed above, the downward movement of the canister moves the actuator pawl downwards to rotate the ratchet wheel clockwise until the count pawl jumps over the second tooth, at which point a count is indicated. *See* Paragraphs 361-362 and 364. This full stroke has occurred just after the canister fires (e.g., is in the canister fire configuration). *See* '552 Publication at 10:26-11:4 ("The counter mechanism of the type described with reference to WO 98/28033 and in

accordance with the present invention must rotate the wheel 30 of the rotary gear by exactly one tooth spacing each time the actuator is depressed. By tooth spacing is mean one tooth pitch, i.e., the radial distance between the same notational point two adjacent teeth on the ratchet-toothed wheel 30. The stroke available for indexing the rotary gear is equal to the full stroke of the actuator 2. Where the metered-dose inhaler is a pressurized inhaler, the stroke available for counting is equal to the full stroke of the medicament canister 6.")

369. I understand that the Parties have proposed different constructions for "canister fire configuration." I understand that the primary difference in these constructions is that Defendants' construction indicates that, in the canister fire configuration, the actuator pawl is below the datum plane line," while Plaintiffs' construction is silent as to this locational requirement. In my opinion, the '552 Publication discloses that the actuator pawl is below the datum plane line when in the canister fire configuration.

370. As discussed above, the '552 Publication makes clear that the invention is essentially the same as the prior art except that the count pawl 60 has been changed. *See id*. at 8:7-8. The prior art embodiments which the '552 Publication improved upon disclose that, in the start or rest position, the actuator pawl is above the datum plane (shown with a red line). Based on the rotation distance, when the actuator pawl is brought into engagement with the first tooth (shown with a purple line), but has not yet begun rotating it (e.g., in the first reset position), it is still above the datum plane line. The '552 Publication discloses that a full stroke, moves the ratchet wheel one full tooth pitch, which would bring the first tooth from the purple line to the green line, at which point the actuator pawl is approximately at or slightly above datum plane line:



371. In my opinion, it would have been obvious to a person of skill in the art to lower the dose counter such that the actuator is below the datum plane line in the fire configuration. The datum plane is generally located at the point where the valve stem sits in the stem block. It is from this reference plane/point that the valve will typically open at a known distance when the cannister is pushed down this minimum distance and the valve opens and allows fluid (propellent and medication) to exit. Bringing the dose counter mechanism closer to this point (and the datum plane) allows for more accurate counting as tolerances from this plane are more controlled as there are less variables. The canister in the '552 Publication, as shown above, moves a single pin to trigger the dose counter. This single pin would be more prone to distortion or bending during use as it has a gap between the actuator and the shelf and this could be exacerbated with the user not pushing the cannister centrally. Arranging the dose counter so that counting occurs very near to valve firing, will create less need for movement and therefore less room for error. Thus, it would have been obvious for a person of skill to move the actuator down, thereby reducing the distance, if any, that must be covered between firing and counting and have it as short as possible to reduce the risk

of distortion during actuation. As the '552 Publication already teaches a dose counter, a person of skill in the art would have a reasonable expectation that the dose counter would still work, and be improved, if the dose counter mechanism was lowered or compressed slightly such that the actuator pawl crossed below the datum plane line in the fire configuration. This change would reduce excessive play in the system.

372. I also understand that the Parties have proposed different constructions of "canister fire sequence." I understand that the primary difference between these constructions is that Defendants' proposed construction requires that, in the rest or start configuration, the count pawl is engaged with a tooth of the ratchet wheel, while the actuator pawl is spaced from the ratchet wheel. As shown in Figure 8a above, in the start position, the '552 Publication discloses that the count pawl is engaged with a tooth of the ratchet wheel, while the actuator pawl is spaced from the ratchet wheel.

373. Accordingly, because this limitation is disclosed, or obvious, under even Defendants' constructions of disputed terms, my opinion remains the same irrespective of which construction is applied.

374. ***Limitation 1G: "wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister."*** As discussed above, in the canister fire configuration, the actuator pawl is below the datum plane. I understand that the Parties have proposed different constructions for the phase "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." However, under either Plaintiffs' proposed construction or Defendants' proposed construction, it is my opinion that the datum plane line is the red line in the above images. And, as discussed above in connection with Limitation 1F, it

would have been obvious to a person of skill in the art to modify the '552 Publication such that when in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

375. For all of these reasons, claim 1 of the '156 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

376. Claim 2 would have been obvious over the '552 Publication. Claim 2 of the '156 Patent depends from claim 1 and recites, "A dose counter as claimed in claim 1 in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations." The '552 Publication describes an existing inhaler with a canister stroke distance of 3.04±0.255 mm. *See* '552 Publication at 11:15-18. The publication further explained that the exemplary inhaler had a start gap of 0.85±0.47. With this gap, inhalers falling on the shorter end of the canister stroke (e.g., 2.785 mm), cannot fully rotate the ratchet wheel, leading to a failure in dose counting. *Id*. at 11:23-12:2. The '552 Publication teaches that placing teeth of pawl 60, 0.6 mm apart, reduces the start gap, reducing the risk of miscounting. A person of skill in the art would have also been aware that, it is optimal to minimize travel distance between firing and counting, otherwise the inhaler might fire, but not count, resulting in incorrect dose counting. The force it requires for a user to fire their inhaler can be quite significant. For example, the '552 Publication discloses that the force required to activate the device is about 15-30 N. If the actuator must be pressed downwards significantly after the user hears and feels the ejection of medication, they are likely to release the device too early, causing undercounting.

377. Thus, a person of skill in the art would be motivated by the teachings in the '552 Publication, and patient experience, to maintain a shorter distance for the actuator device to move in order to register a dose count, and would it require no more than routine optimization to arrive

at a distance of less than 1mm, particularly as the '552 Publication already taught improvements in accuracy where the travel distance between teeth of the count pawl is less than 1mm. Thus, claim 2 of the '156 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

378. Claims 9 and 11-13 of the '156 Patent, which depend directly or indirectly from claim 1 would have been obvious for the same reasons set forth with respect to claim 1, above as well as the reasons set forth in detail below.

379. Claim 9 of the '156 Patent depends from claim 1 and recites "A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween." The '552 Publication discloses that the count pawl and ratchet wheel are arranged such that "[p]referably, the pawl 60 prevents rotation of the rotary gear." *See* '552 Publication at 14:20-21. Accordingly, this limitation is disclosed by the '552 Publication. Thus, claim 9 of the '156 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

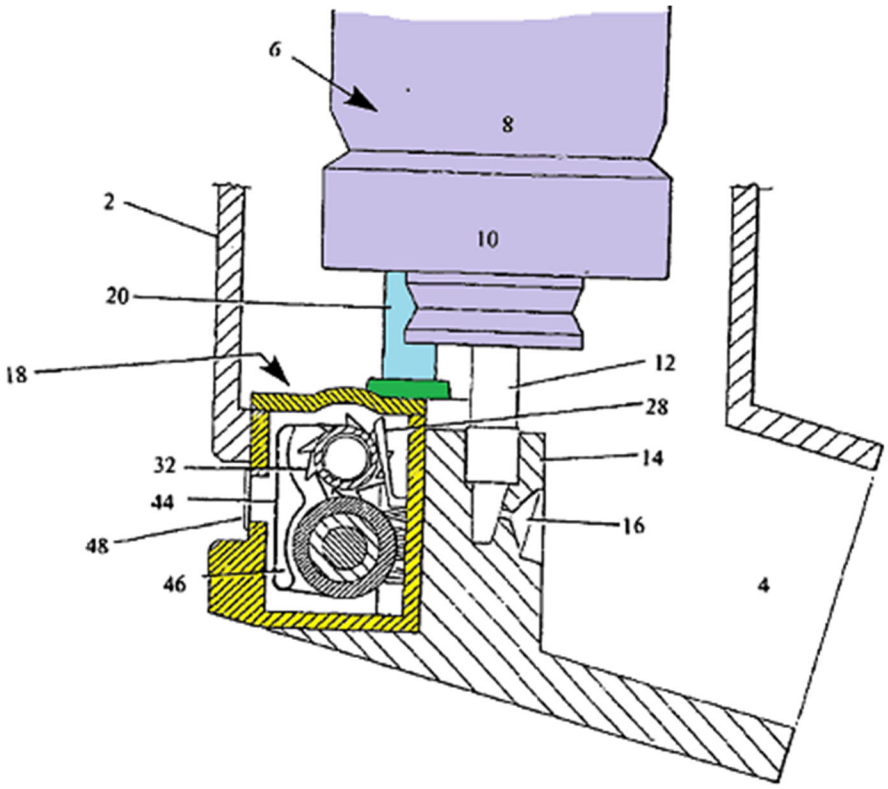
380. Claim 11 depends from claim 1 of the '156 Patent and recites, "[a]n inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter." The '552 Publication discloses this limitation. For example, it discloses the use of a medicament canister in the body, along with a dose counter. *See* 13:14-22, Fig. 9. Thus, claim 11 of the '156 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

381. Claim 12 depends from Claim 11 of the '156 Patent and recites, "[a]n inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body

of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator."

382. For the reasons discussed in detail in Section XVI.D, below, this claim is structurally impossible and indefinite.

383. I understand that Plaintiffs have proposed a construction that rewrites the claim, whereby "the body," when used the second time only, refers to "the dose counter body." If the claim is not found to be indefinite, and Plaintiffs' construction is adopted, the '552 Publication discloses this limitation. As discussed above, the '552 Publication makes clear that the invention is essentially the same as the prior art except that the count pawl 60 has been changed. *See id*. at 8:7-8. Figure 3 discloses the prior art on which the '552 Publication improves. Figure 3 discloses a separate counter chamber (yellow). The entirety of the dose counter 18, including "the body of the dose counter, the ratchet wheel, and the actuator are located inside the separate counter chamber. The actuation member 20 (blue) extends through an aperture (green), such that motion from the canister (light purple) can be translated to the dose counter.

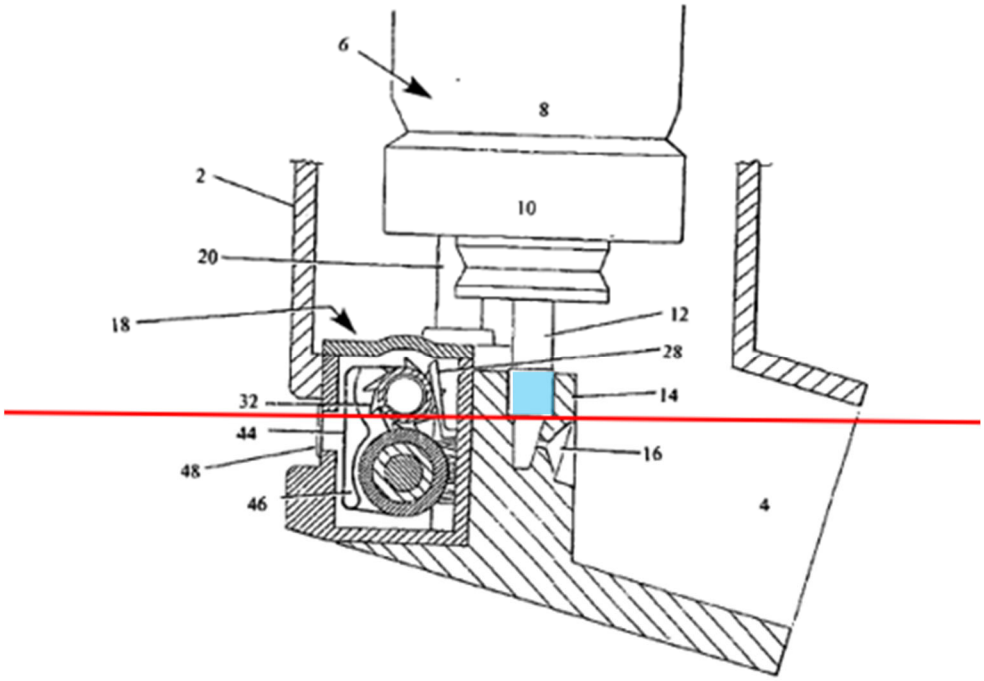


384. Accordingly, to the extent this claim is not indefinite, and Plaintiffs' construction is adopted, the '552 Publication renders claim 12 obvious.

385. I understand the Parties have proposed different constructions for "separate counter chamber." I understand the primary difference between the two constructions is that Defendants' proposed construction requires the chamber be formed by the inner walls of the body of the inhaler, while Plaintiffs' proposed construction merely requires a separate chamber. This limitation is met under Plaintiffs' construction by the counter chamber shown in yellow in Figure 3, above. In addition, as shown in Figure 3, this chamber is formed by the inner walls of the inhaler body, thus, to the extent this claim is found definite, my opinion does not change if Defendant's construction of "separate counter chamber" is adopted.

386. Claim 13 depends from claim 1 of the '156 Patent and recites "The dose counter of claim 1, wherein the shoulder is a bottom surface within the valve stem block and the datum plane

is perpendicular to a direction of the movement of the medicament canister." When drawn in accordance with either Party's construction, the datum plane line disclosed in the '552 Publication is represented by the red line in the below image.



387. As discussed above, in use, the canister is moved by the user depressing it, in other pressing downwards. Thus, as can be seen in the image, the datum plane line is perpendicular to the movement of the canister. In addition, the datum plane line is the bottom surface of the valve stem block, shown in blue. Thus, claim 13 of the '156 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

C. <u>Claims 1-2, 9, and 11-13 Would Have Been Obvious Over the '406 Publication</u>

388. In my opinion, claims 1-2, 9, and 11-13 of the '156 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '406 Publication.

389. I understand that the Parties have proposed competing constructions for various terms in the '156 Patent. However, because it is my opinion that the Defendants' ANDA Products

practice the dose counter disclosed in the '406 Publication, to the extent Plaintiffs contend that Defendants' ANDA Products infringe under any construction adopted by the Court, my opinion will remain unchanged.

390. ***Preamble: "A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising."*** To the extent the preamble is limiting, the '406 Publication discloses this limitation. *See, e.g.,* '406 Publication at Abstract, [0067], [00106], [00149], and Fig. 27.

391. ***Limitation 1A: "a ratchet wheel having a plurality of circumferentially spaced teeth."*** I understand that Plaintiffs contend that the "units teeth ring" of Defendants' ANDA Products are "a ratchet wheel comprising a plurality of circumferentially spaced teeth." Plaintiffs' Infringement Contentions to Cipla at Appendix 3, p. 6. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes a "units teeth ring," which performs the same function in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

392. ***Limitation 1B: "an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate."*** I understand that Plaintiffs contend that the indexer of Defendants' ANDA Products is the claimed "actuator" and that the indexer is arranged to engage with a first tooth of the alleged ratchet wheel ("units teeth ring"). Plaintiffs' Infringement

Contentions to Cipla at Appendix 3, pp. 10-12, 15-17. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes an "indexer," which performs the same function, and interacts in the same way with the "units teeth ring" in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

393. ***Limitation 1C: "a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth."*** I understand that Plaintiffs contend that protrusions on the bottom of the indexer of Defendants' ANDA Products are the "count pawls" and that the indexer is arranged to engage with a second tooth of the alleged ratchet wheel ("units teeth ring"). Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 19-21, 24-25. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes an "indexer," which performs the same function, and interacts in the same way with the "units teeth ring" in both the '406 Publication and Defendants' ANDA Products. *See id*. In addition, like the indexer in Defendants' ANDA Products, the indexer of the '406 Publication includes "protrusions" (326) on the bottom. *Id.* Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

394. ***Limitation 1D: "a dosage indicator associated with the count pawl."*** I understand that Plaintiffs contend that protrusions on the bottom of the indexer of Defendants' ANDA Products are the "count pawls" which interact with the "units teeth ring," or the "tens cone," or both the "units teeth ring" and the "tens cone." Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 27-28. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes protrusions on the bottom of the indexer, a "units teeth ring," and a "tens cone," each of which performs the same function, and interacts in the same way with each other in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

395. ***Limitation 1E: "wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth."*** I understand that Plaintiffs contend that the indexer in Defendants' ANDA Products is "arranged to define a first reset position in which one protrusion on the bottom of the indexer is borough into engagement with the first tooth of the units teeth ring." Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 31. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes protrusions on the bottom of the indexer and a units teeth ring, each of which performs the same function, and interacts in the same way with each other, in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the

doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

396. ***Limitation 1F: "wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count."*** I understand that Plaintiffs contend that the indexer in Defendants' ANDA Products are an "actuator pawl" and is "arranged such that, during a canister fire sequence, when the indexer is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration." Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 33. I understand that Plaintiffs also contend that Defendants' ANDA Products include a position where "the indexer [is] in a third position after the second position, [where] the protrusion on the bottom of the indexer resiliently jumps over the second tooth of the units teeth ring, and the dose counter reaches the count configuration, whereby the units display ring and tens cones (separately or in combination) have indicated a count." Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 36. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes protrusions on the bottom of the indexer and a units teeth ring, each of which performs the same function, and interacts in the same way with each other, in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent

Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

397. ***Limitation 1G: "wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister."*** I understand that Plaintiffs contend that a protrusion on the bottom of the indexer in Defendants' ANDA Products is the "actuator pawl" and that in the "canister fire configuration" the protrusion is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister. Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 39-40. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes protrusions on the bottom of the indexer that perform the same function in both the '406 Publication and Defendants' ANDA Product. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication. Thus, claim 1 of the '156 Patent would have been obvious over the '406 Publication.

398. Claim 2 depends from claim 1 of the '156 Patent and recites, "A dose counter as claimed in claim 1 in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations." I understand that Plaintiffs contend that a protrusion on the bottom of the indexer in Defendants' ANDA Products is the "actuator pawl" and that this protrusion travels less than 1 mm relative to the body between the canister fire and count configurations. Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 44-46. As

discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes protrusions on the bottom of the indexer that perform the same function, in the same way, in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication. Thus, claim 2 of the '156 Patent would have been obvious over the '406 Publication.

399. Claim 9 depends from claim 1 of the '156 Patent and recites "A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween." I understand that Plaintiffs contend that a protrusion on the bottom of the indexer in Defendants' ANDA Products is the "count pawl," the units teeth ring is a "ratchet wheel," and that this protrusion only permits the units teeth ring to rotate in one direction. Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 49-51. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes protrusions on the bottom of the indexer and the units teeth ring perform the same function and interact with each other in the same way, in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication. Thus, claim 9 of the '156 Patent would have been obvious over the '406 Publication.

400. Claim 11 depends from claim 1 of the '156 Patent and recites, "[a]n inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1." The '406 Publication discloses, or renders obvious, the dose counter as claimed in claim 1, for the reasons discussed above. The '406 Publication also discloses an inhaler body arranged to retain a medicament canister of predetermined configurations. *See, e.g.,* '406 Publication at Abstract, [0067], [00106], [00149], and Fig. 27. Thus, claim 11 of the '156 Patent would have been obvious over the '406 Publication.

401. Claim 12 depends from Claim 11 of the '156 Patent and recites, "[a]n inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator."

402. For the reasons discussed in detail in Section XVI.D, below, this claim is structurally impossible and indefinite.

403. I understand that Plaintiffs have proposed a construction that rewrites the claim, whereby "the body," when used the second time only, refers to "the dose counter body." If the claim is not found to be indefinite and Plaintiffs' construction is adopted, the '406 Publication discloses, or renders obvious, this limitation. I understand that Plaintiffs contend that the lid of the housing in Defendants' ANDA Products divides the body of the inhaler into a canister-receiving portion and a separate counter chamber. Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 58-59. Plaintiffs further contend that the body of the dose counter, the units teeth ring, and the indexer are all located in the housing below the lid. *Id*. at 61-62. Plaintiffs

contend that the lid is "equivalent to wall surfaces separating the canister-receiving portion and the counter chamber" of Defendants' ANDA Product. *Id.* at 65-68. Plaintiffs contend that the lid includes a hole through which the castellations of the indexer pass, which is the claimed aperture. *Id*. at 69-71. Finally, Plaintiffs contend that the castellations of the indexer are "actuation members" that extend through the aperture to transmit canister motion to the actuator. *Id*. at 74-76.

404. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes a housing, lid, castellations, and an aperture through which the castellations pass. *Id*. These structures and components perform the same function and interact with each other, and the other parts of the dose counter including the indexer and units teeth ring, in the same way, in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

405. Claim 13 depends from claim 1 of the '156 Patent and recites "The dose counter of claim 1, wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister."

406. I understand that Plaintiffs contend that the datum plane in Defendants' ANDA Products is perpendicular to the movement of the medicament canister. Plaintiffs' Infringement Contentions to Cipla at Appendix 3, pp. 78-79. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes the same

datum plane, and same directional movement of the medicament canister. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication. Thus, claim 1 of the '156 Patent would have been obvious over the '406 Publication.

D. Claim 12 of the '156 Patent is Indefinite

407. The claim term "body" appears in dependent claims 11 and 12, as well as independent claim 1. However, the term is used inconsistently throughout these claims.

408. The preamble of claim 1 recites: "A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister . . ." Thus, it would be clear to a person of skill in the art that, in claim 1, a "body" refers to the body of the inhaler.

409. Claim 11 recites, "an inhaler comprising the body arranged to retain the medicament canister . . ." Once again, a person of skill in the art would understand "the body" to be referring to the body of the inhaler (i.e., the body referred to in claim 1).

410. The preamble of claim 12 recites, "An inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber . . ." Again, a person of skill in the art would understand that "the body" refers to body of the inhaler, (i.e., again, the body referred to in claim 1 and 11).

411. The problem arises with the second recitation of the "the body" in claim 12. Claim 12 recites in part, "An inhaler as claimed in claim 11 in which **the body** includes a canister-receiving portion and a separate counter chamber; **the body,** ratchet wheel and actuator being located inside the counter chamber, . . ." As a result, the recited portion "the body, ratchet wheel, and actuation being located inside the counter chamber," requires each of these components to be located inside "the body." Thus, as written, "the body" can have only one meaning: "body of the

inhaler." Thus claim 12 is inoperable because the "body of the inhaler" cannot be located inside of the counter chamber that is, in turn, located in the "body of the inhaler."

412. I understand that Plaintiffs have argued that "the body" merely lacks antecedent basis (e.g., it was not properly introduced earlier in the claim) and was intended to refer to a different body—specifically the body of the dose counter. However, nothing in the claims or specification would lead a person of skill in the art to that conclusion. The specification describes of number of "bodies" including "main body of the dose counter" ('289 Patent at 3:13, 3:51-52, 10:50-51); "main body of the incremental count system" (*id*. at 6:46, 10:43, 11:11-12, 11:18, 11:30, 12:31, 14:23, 16:6-7, 17:14-15); body for retaining a medicament store (id. at 7:28, 7:63); "the main canister body" (id. at 9:19-21); "inhaler main body" (*id*. at 6:24, 10:36-37, 11:19, 11:24-25, 11:33-34, 12:31); and "actuator body" (*id*. At 1:33-34). In fact, the term "body" appears over 70 times. Moreover, a person of skill in the art would have no reason to attempt to guess at what was intended, when the claims themselves already clearly defined body. The mere fact that the claim was written poorly, such that it is inoperable and indefinite, does not change the fact that "the body" was clearly defined in the claims. Even if a POSA were to attempt to speculate on which other "body" may have been intended, the number of different "bodies" described in the specification and the frequency in which the term is used prohibits a POSA from making that determination with any confidence.

413. I understand that nonsensical or impossible claims are indefinite as a matter of law, and that claims should be construed as written. Accordingly, in my opinion, claim 12 of the '156 Patent is indefinite.

XVII. INVALIDITY OF THE '808 PATENT

414. The '808 Patent is entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," and is directed to a dose counter with an incremental movement using a regulator to provide resistance forces. *See generally* '808 Patent.

415. I understand that Plaintiffs are asserting claims 1 and 27-28 from the '808 Patent.

416. Claim 1 is the only independent claim of the '808 Patent. Claims 27-28 depend, either directly or indirectly, from Claim 1. Claim 1 recites:

> A dose counter for an inhaler, the dose counter having
> a counter display arranged to indicate dosage information,
> a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,
> wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

'808 Patent, claim 1.

417. Claim 27 of the '808 Patent recites:

> The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.

418. Claim 28 of the '808 Patent recites:

> The dose counter as claimed in claim 27 in which the resistance force of greater than 0.3 N.

419. As discussed in detail below, in my opinion, each asserted claim of the '808 Patent is invalid in view of the prior art.

420. I understand that the Parties have disputed the construction of several phrases in the '808 Patent, including "counter display arranged to indicate dosage information," "first station," and "second station." As the '552 Publication and '950 Publication are both directed to tape-based dose counters ("counter display arranged to indicate dosage information") with spindles from which the tape moves ("first station" and "second station") that satisfy these claims even

under Defendants' constructions, my opinion remains unchanged under either party's proposed construction of these terms.

A. Claim 1 of the '808 Patent is Anticipated by the '552 Publication

421. In my opinion, claim 1 of the '808 Patent is invalid at least because it is anticipated under 35 U.S.C § 102(b) by the '552 Publication.

422. ***Preamble: "A dose counter for an inhaler".*** To the extent the preamble is limiting, the '552 Publication discloses a dose counter for an inhaler, the dose counter having a display to indicate dosage information (tape). *See, e.g.*, '552 Publication at 4:20-31, 8:7-8, 9:9-18; Fig. 6.

423. ***Limitation 1A: "the dose counter having a counter display arranged to indicate dosage information,".*** The '552 Publication discloses a dose counter for an inhaler, the dose counter having a display to indicate dosage information (tape). *See, e.g.*, '552 Publication at 4:20-31, 8:7-8, 9:9-18; Fig. 6.

424. ***Limitation 1B: "a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,".*** The '552 Publication further discloses a drive system moving the display tape from a first station (tape stock bobbin) to a second station (reel shaft). *Id*.

425. For example, Figure 5 of the '552 Publication, reproduced below, discloses a dose counter for an inhaler. As illustrated in Figure 6, reproduced below, the '552 Publication includes a counter display arranged to indicate dosage information. Figure 6 illustrates a tape annotated with dosage information. Figure 5 illustrates the drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input.

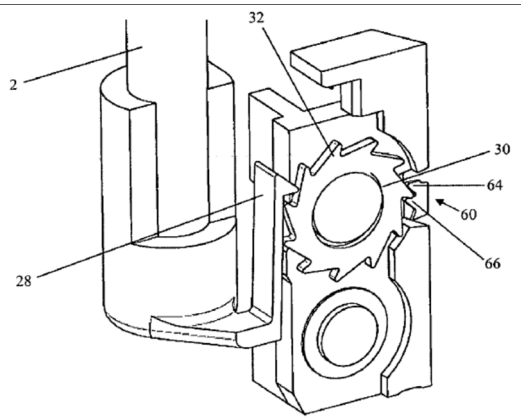


Figure 5

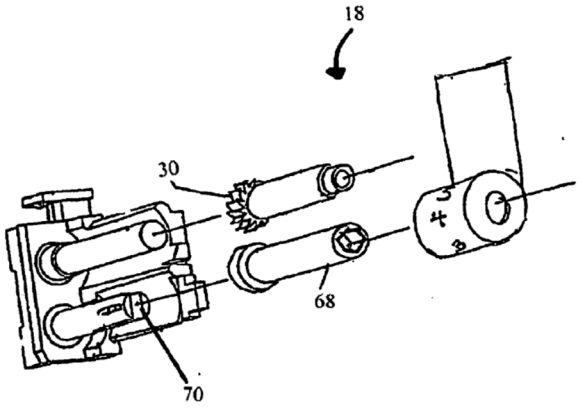


Fig. 6

426. As explained in the '552 Publication, the "dose counter of the present invention is based on that set out in Figs 3 and 4 described herein above except that the pawl 60 has been modified." *See* '552 Publication at 8:7-18. The dose counter has a control surface that acts as a regulator: "the dose counter 18 of the present invention preferably further comprises a control surface to regulate the position of engagement and disengagement between the driver 28 and the wheel 30." *See* '552 Publication at 8:26-28. Further, a pawl 60 comprises at least two ratchet teeth 64, 66. *See* '552 Publication at 9:1-7. The two ratchet teeth 64, 66 are radially spaced with respect to the ratchet-toothed wheel 30 such that one and the same tooth engages with the ratchet teeth 32 of the wheel following each step of the step-wise rotary motion of the rotary gear. *Id*. An aerosol canister 6 is depressed to cause displacement of the actuator 20 (also labeled 2) in the form of a spring-loaded plunger 22 and 24. *See* '552 Publication at 9:21-31.

427. ***Limitation 1C: "wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements."*** The '552 Publication discloses a regulator—forks inside the tape

stock bobbin—regulating the motion of the display to incremental movements. *See, e.g.*, '552 Publication at 9:9-18; Fig. 6.

428. I understand that the Parties have agreed that the term "regulator" should be construed to mean "a structure of the dose counter that modulates motion of the counter display." I also understand that the Parties have agreed that the term "regulate motion of the counter display" means "modulate motion of the counter display." I have applied these constructions in my analysis.

429. The '552 Publication explains that "Fig. 6 shows an exploded view of the dose counter 18 which is held taut by the action of the split hub 70." '552 Publication at 9:9-12. Notably, split hub 70 includes at least one protrusion, visible in Figure 6. As shown below, this extending protrusion shown in Figure 6 of the '552 Publication (left) is essentially identical to the protrusion shown in Figure 6A of the '808 Patent (right), and is even located in the same location on the split hub.

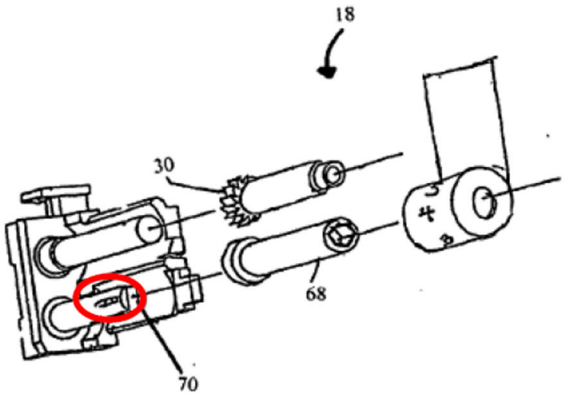


Fig. 6

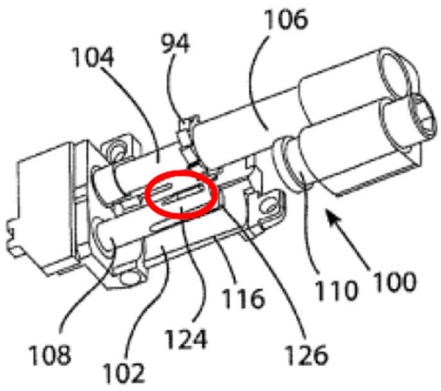


FIG. 6A

430. Stock Bobbin 68 of the '552 Publication, like stock bobbin 110 of the '808 Patent, is shaped irregularly, like a hexagon at the entrance to the bobbin. Although the '552 Publication does not explicitly recite the purpose of the protrusions on the split hub, it is apparent that its

purpose is to contact the interior of the stock bobbin 68, and modulate motion of the tape to prevent unwanted unrolling (e.g., to modulate it to incremental movement). This is confirmed by the '950 Publication, which is directed to a dose counter with the same split hub, same protrusions 146, and same stock bobbin 132. *See* '950 Publication at Fig. 15. The '950 Publication refers to these protrusions as "radially nubs for creating resilient resistance to rotation of the bobbin 132 on the shaft 142." *Id*. at [0057]. A comparison of the '950 Publication and the '552 Publication below shows that the structures are identical, but for the inclusion of a clutch spring in Figure 15.

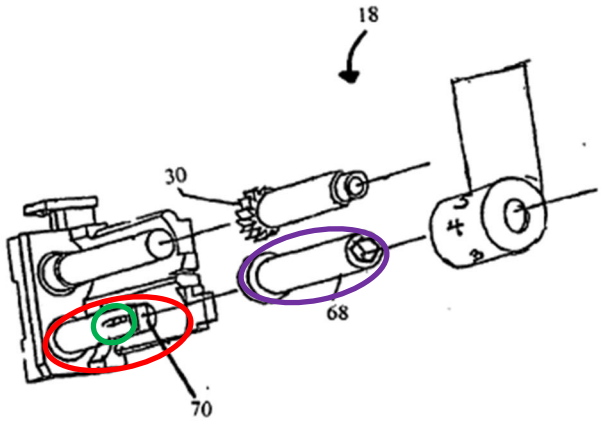


Fig. 6

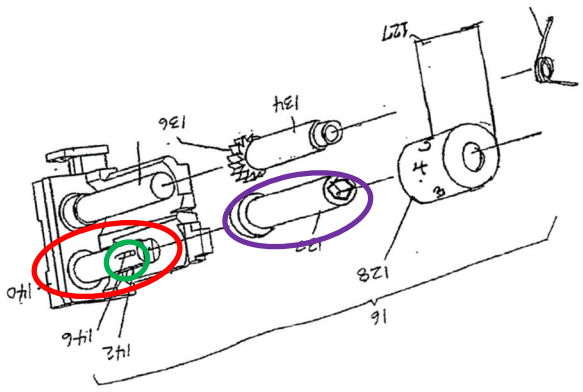


Fig. 15

431. In the above images, the protrusions, or radially nubs, are circled in green, the split hub is circled in red, and the stock bobbin is circled in purple. Thus, my opinion that the protrusion disclosed in Figure 6 of the '552 Publication is a "regulator" that is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements is confirmed by the '950 Publication.

432. I understand that Plaintiffs have contended that the structure disclosed in the '552 Publication is not a "regulator" because it allegedly does not include "a wavelike engagement surface with concavities which engage against" the protrusions. Plaintiffs' Response to Cipla's Invalidity Contentions at 282. I disagree. The claim, as construed, merely requires "a structure of

the dose counter that modulates motion of the counter display which is arranged to act upon the counter display at the first station to modulate motion of the counter display at the first station to incremental movements." The protrusions disclosed in the '552 Publication are included for that purpose. *See* '950 Publication at [0057]. The mere fact that they do so in a different way (frictional engagement with a surface that may, or may not have a wavelike surface) is irrelevant. That the method of "regulation" is irrelevant is confirmed by Plaintiffs own allegation that the leaf spring in Defendant's ANDA Products (which lacks any protrusions or wavelike surfaces) is a "regulator". *See* Plaintiffs' Infringement Contentions to Cipla at Appendix 4, at 17-19.

433. It is my opinion that each element of claim 1 is described by the '552 Publication. Claim 1 is therefore anticipated by the '552 Publication.

B. The Asserted Claims of the '808 Patent Would Have Been Obvious over the '552 Publication

434. To the extent that any of the elements of claim 1 of the '808 Patent are not expressly disclosed by the '552 Publication, the element, and the claim as a whole, would have been obvious in view of the knowledge of a POSA.

435. As discussed in Section XVII.A, above, the '552 Publication discloses every element of claim 1 of the '808 Patent. However, I understand that Plaintiffs have contended that the '552 Publication does not disclose a "regulator." I disagree, for the reasons stated above. However, to the extent that it does not explicitly disclose a "regulator" the '552 Publication still renders that limitation obvious.

436. As discussed above, several prior art references, including the '950 Publication taught that the protrusions, as seen in the '552 Publication, were known to be used to provide frictional resistance to rotating. *See* '950 Publication at [0057]. To the extent that this disclosure of protrusions creating frictional resistance does not explicitly disclose a "regulator," it would have

been obvious to a person of skill in the art to include ridges, or other shapes on the interior of the stock bobbin to further modulate movement by creating additional resistance. In fact, this solution had been done before. For example, the Severent Diskus inhaler (which has been marketed since 1998 and is a well-known inhalation device with which any person of skill in the art would be familiar), similarly used a bobbin (with teeth) on a spindle. The interior of the spindle included ridged elements for regulating movement of the drive system for advancing the ribbon. An image of this toothed bobbin is shown below.

437. For at least these reasons, claim 1 of the ’808 Patent would have been obvious over the ’552 Publication and the knowledge of the POSA.

438. Claim 27 depends from claim 1 and recites, “The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.” As discussed above, the dose counter disclosed in the ’552 Publication anticipates, or renders obvious, every element of claim 1 of the ’808 Patent. To the extent this limitation is not inherently met by the disclosure of the ’552 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the

counter display forward upon actuation of the inhaler. Thus, claim 27 of the '808 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

439. Claim 28 depends from claim 27 and recites, "The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N." As discussed above, the dose counter disclosed in the '552 Publication anticipates, or renders obvious, every element of claim 1 of the '808 Patent. To the extent this limitation is not inherently met by the disclosure of the '552 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler. Thus, claim 28 of the '808 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

C. Claim 1 of the '808 Patent is Anticipated by the '950 Publication

440. In my opinion, claim 1 of the '808 Patent is invalid at least because it is anticipated under 35 U.S.C § 102(b) by the '950 Publication.

441. ***Preamble: "A dose counter for an inhaler".*** To the extent the preamble is limiting, the '950 Publication discloses a dose counter for an inhaler; the dose counter has a display to indicate dosage information (the "display tape"). *See* '950 Publication at Figs. 5, 14, 15.

442. ***Limitation 1A: "the dose counter having a counter display arranged to indicate dosage information,"***. The '950 Publication discloses a dose counter for an inhaler; the dose counter has a display to indicate dosage information (the "display tape"). *See* '950 Publication at Figs. 5, 14, 15.

443. ***Limitation 1B: "a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,"***. The '950 Publication discloses a drive system moving the display tape from a first station

(described as the "tape stock bobbin") to a second station ("reel shaft"). *See* '950 Publication at [0010] ("In a preferred form, the does counter includes a bobbin, a rotatable spool, and a rolled ribbon received on the bobbin, rotatable about an axis of the bobbin. The ribbon has indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the bobbin. The dose counter also includes teeth extending radially outwardly from the spool into the predetermined path of the pawl so that the spool is rotated by the pawl and the ribbon advanced onto the spool during the metering of a dose to the mouthpiece."); *see also* [0054] ("The dose counting system 16 is mounted to the hopper 42 and includes a ribbon 128, having successive numbers or other suitable indicia printed thereon, in alignment with a transparent window 130 provided in the housing 18 (see FIG. 2). The dose counting system 16 includes a rotatable bobbin 132, an indexing spool 134 rotatable in a single direction, and the ribbon 128 rolled and received on the bobbin 132 and having a first end 127 secured to the spool 134, wherein the ribbon 128 unrolls from the bobbin 132 so that the indicia is successively displayed as the spool 134 is rotated or advanced.").

444. ***Limitation 1C: "wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements."*** The '950 Publication discloses a regulator—forks and nubs inside the tape stock bobbin—regulating the motion of the display to incremental movements. See, e.g., '950 Publication at [0057], Fig. 15.

445. Figure 15 of the '950 Publication, discloses a dose counter display system 16 which includes a bobbin 132 and an indexing spool 134 that are mounted on shafts 142 and 144, respectively. The bobbin shaft 142 is forked and includes radially extending nubs 146 that are

described by the '950 Publication as "creating a resilient resistance to rotation of the bobbin 132 on the shaft 142."

446. As shown below, the "radially extending nubs" shown in Figure 15 of the '950 Publication (left) are essentially identical to the protrusion shown in Figure 6A of the '808 Patent (right), and are even located in the same location on the forked bobbin shaft.

447.

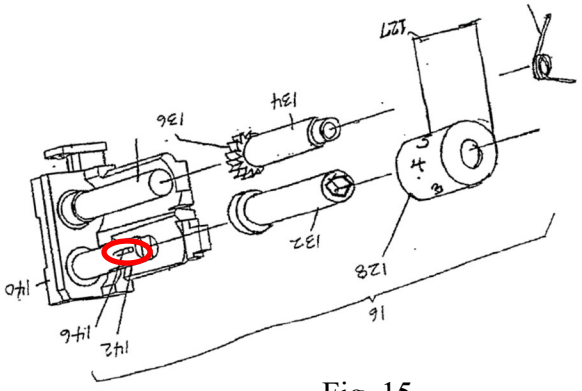


Fig. 15

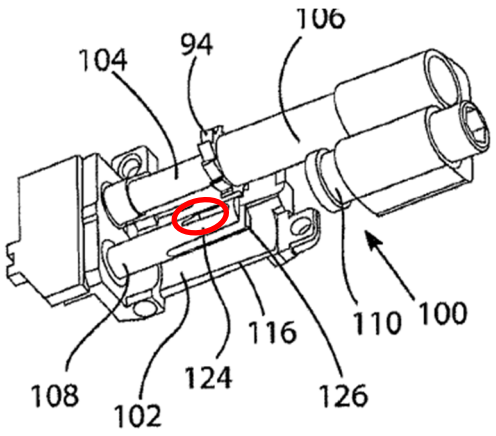


FIG. 6A

448. I understand that Plaintiffs have contended that the "radially extending nubs" disclosed in the '950 Publication are not "regulator" because the '950 Publication allegedly does not disclose "a wavelike engagement surface with concavities which engage against" the protrusions. Plaintiffs' Response to Cipla's Invalidity Contentions at 293-94. I disagree. The claim, as construed, merely requires "a structure of the dose counter that modulates motion of the counter display which is arranged to act upon the counter display at the first station to modulate motion of the counter display at the first station to incremental movements." The radially extending nubs in the '950 Publication are included for that purpose. *See* '950 Publication at [0057]. The mere fact that they do so in a different way (frictional engagement with a surface that may, or may not have a wavelike surface") is irrelevant. That the method of "regulation" is

irrelevant is confirmed by Plaintiffs own allegation that the leaf spring in Defendant's ANDA Products (which lacks any protrusions or wavelike surfaces) is a "regulator". *See* Plaintiffs' Infringement Contentions to Cipla at Appendix 4, at 17-19.

449. I also understand that Plaintiffs contend that the radially extending nubs are not a "regulator" because, during prosecution, the patentees distinguished these nubs, from the "regulators" of the '808 Patent. First, I understand that, a reference being in front of an examiner during prosecution does not necessarily mean that it did not disclose the claimed limitation. Second, I have reviewed portions of the prosecution history, and the primary discussion between the patentees and the examiner were whether the limitations could be met if the '950 Publication disclosed complementary features on the interior of the bobbin, and that it was reasonable to infer the presence of such features. *See* '808 Prosecution History at Dec. 16, 2016 Office Action, March 15, 2017 Response to Office Action, April 11, 2017 Office Action, July 6, 2017 Office Action Response, July 7, 2019 Office Action, Sept. 9, 2019 PTO Board Decision. However, in my opinion, the axial nubs are disclosed to provide friction against rotation, even without complementary features. *See* '950 Publication at [0057]. The provided friction, at a minimum, works with the other features of the device (ratchet wheel, clutch spring, actuator pawl) to move the counter display tape forward incrementally, without unwanted unwinding.

450. It is my opinion that each element of claim 1 is described explicitly or implicitly by the '950 Publication. Claim 1 is therefore anticipated by the '950 Publication.

D. The Asserted Claims of the '808 Patent Would Have Been Obvious Over the '950 Publication

451. To the extent that any of the elements are not taught or suggested by the '950 Publication, the element, and the claims as a whole, would have been obvious in view of the knowledge of a POSA.

452. As discussed in Section XVII.C, above, the '950 Publication discloses every element of claim 1 of the '808 Patent. However, I understand that Plaintiffs have contended that the '950 Publication does not disclose a "regulator." I disagree, for the reasons stated above. However, to the extent that it does not explicitly disclose a "regulator" the '950 Publication still renders that limitation obvious.

453. As discussed above, several prior art references, including the '950 Publication, taught that the protrusions, or radially extending nubs, were known to be used to provide frictional resistance to rotating. *See* '950 Publication at [0057]. To the extent that this disclosure of protrusions creating frictional resistance does not explicitly disclose a "regulator," it would have been obvious to a person of skill in the art to include ridges, or other shapes on the interior of the stock bobbin to further modulate movement by creating additional resistance. In fact, this solution was so well known that it had been done before. For example, the Diskus inhaler (which has been marketed since 1998 and is a well-known inhalation device with which any person of skill in the art would be familiar), similarly used a bobbin (with teeth) on a spindle. The interior of the spindle included ridged elements for regulating movement of the ribbon in a controlled or incremental manner. An image of this toothed bobbin is shown below.

454. For at least these reasons, claim 1 of the '808 Patent would have been obvious over the '950 Publication and the knowledge of the POSA.

455. Claim 27 depends from claim 1 and recites, "The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display." As discussed above, the dose counter disclosed in the '950 Publication anticipates, or renders obvious, every element of claim 1 of the '808 Patent. To the extent this limitation is not inherently met by the disclosure of the '950 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler. Thus, claim 27 of the '808 Patent would have been obvious over the '950 Publication and the knowledge of the POSA.

456. Claim 28 depends from claim 27 and recites, "The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N." As discussed above, the dose counter disclosed in the '950 Publication anticipates, or renders obvious, every element of claim 1 of the '808 Patent. To the extent this limitation is not inherently met by the disclosure of the '950 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler. Thus, claim 27 of the '808 Patent would have been obvious over the '950 Publication and the knowledge of the POSA.

E. The Asserted Claims of the '808 Patent Would Have Been Obvious Over the '406 Publication

457. In my opinion, claims 1 and 27-28 of the '808 Patent are invalid at least because they would have been obvious under 35 U.S.C § 103 in view of the '406 Publication.

458. I understand that the Parties have proposed competing constructions for various terms in the '808 Patent. However, because it is my opinion that the Defendants' ANDA Products practice the dose counter disclosed in the '406 Publication, to the extent Plaintiffs contend that Defendants' ANDA Products infringe under any construction adopted by the Court, my opinion will remain unchanged.

459. ***Preamble: "A dose counter for an inhaler".*** To the extent the preamble is limiting, the '406 Publication discloses this limitation. *See, e.g.,* '406 Publication at Abstract, [0067], [00106], [00149], and Fig. 27.

460. ***Limitation 1A: "the dose counter having a counter display arranged to indicate dosage information,"***. I understand that Plaintiffs contend that the "counter display arranged to indicate dosage information" of Defendants' ANDA Products is "the units display ring," or alternatively, the "tens cone," or alternatively the "units teeth ring" and "tens cone" together. Plaintiffs' Infringement Contentions to Cipla at Appendix 4, pp. 3-8. As discussed in detail above, it is my opinion that the Defendants' ANDA Products, practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes a "units teeth ring" and a "tens cone" which perform the same purpose in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

461. ***Limitation 1B: "a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,"***. I understand that Plaintiffs contend that the "lid," "indexer," and "units teeth ring" comprise a drive system in Defendants' ANDA Products which move the units display ring and/or

the tens cone in a first direction incrementally. Plaintiffs' Infringement Contentions to Cipla at Appendix 4, pp. 9-11. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products include a "lid," "indexer," and "units teeth ring" which perform the same function in both the '406 Publication and Defendants' ANDA Products. *See id*. Defendants next contend that the "first station" in Defendants' ANDA Products is a position showing a first number and the "second station" is a position showing a second number. *See* Plaintiffs' Infringement Contentions to Cipla at Appendix 4, pp. 12-13. Like the Defendants' ANDA Products, the '406 Publication discloses a "units teeth ring" and a "tens cone" which rotate and display different numbers with each incremental rotation. *See Supra* at Section XII. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication.

462. ***Limitation 1C: "wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements."*** I understand that Plaintiffs contend that the "leaf spring" of Defendants' ANDA Products is "a regulator . . . arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements. Plaintiffs' Infringement Contentions to Cipla at Appendix 4, pp. 17-19. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XII. The '406 Publication, like Defendants' ANDA Products, includes a "leaf spring" which performs the same function in both the '406 Publication and Defendants' ANDA Products. *See id*. Accordingly, to the extent Plaintiffs contend this

limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication. Thus, claim 1 of the '808 Patent would have been obvious over the '406 Publication.

463. Claim 27 depends from claim 1 and recites, "The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display." I understand that Plaintiffs contend that the "leaf spring" of Defendants' ANDA Products is a regulator which provides a resistance force of greater than 0.1 N against movement of the counter display. Plaintiffs' Infringement Contentions to Cipla at Appendix 4, pp. 22-23. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes a "leaf spring" which performs the same function in both the '406 Publication and Defendants' ANDA Product. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication. Thus, claim 27 of the '808 Patent would have been obvious over the '406 Publication.

464. Claim 28 depends from claim 27 and recites, "The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N." I understand that Plaintiffs contend that the "leaf spring" of Defendants' ANDA Products is a regulator which provides a resistance force of greater than 0.3 N against movement of the counter display. Plaintiffs' Infringement Contentions to Cipla at Appendix 4, pp. 25-27. As discussed in detail above, it is my opinion that the Defendants' ANDA Products practice the invention disclosed in the '406 Publication. *See Supra* at Section XIII. The '406 Publication, like Defendants' ANDA Products, includes a "leaf spring" which performs the same function in both the '406 Publication and Defendants' ANDA

Product. *See id*. Accordingly, to the extent Plaintiffs contend this limitation is present, literally or under the doctrine of equivalents, in Defendants' ANDA Products, this limitation is also disclosed by, or obvious over, the '406 Publication. Thus, claim 28 of the '808 Patent would have been obvious over the '406 Publication.

F. Under Plaintiffs' Construction of "Counter Display Arranged to Indicate Dosage Information," the Asserted Claims Lack Written Description Support and are not Enabled

465. I understand that the parties have proposed different constructions for the phrase "counter display arranged to indicate dosage information." I understand that one of the differences between the parties' constructions is that Defendants' construction identifies the "counter display" as a single structure, while Plaintiffs' allows the display to be comprised of multiple displays or components, which may move independently of each other.

466. Under Plaintiffs' proposed construction, the claim would encompass devices including a device having two separate displays. For example, such a device could include two separate tapes, one displaying tens and one displaying units (as shown by the redline splitting the tape in Figure 6E of the '808 Patent). In order to display remaining doses, each of these tapes would need to move independently of each other. For example, the tape displaying the tens would move only every ten ejections, while the tape displaying units would move with every ejection.

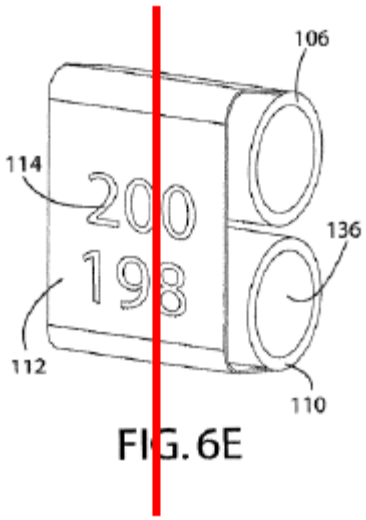


FIG. 6E

467. I have reviewed the specification of the '808 patent, and there is no disclosure of multiple displays. Nor is there any disclosure or teaching of mechanisms for independently moving separate displays. Accordingly, the Asserted Claims of the '808 Patent are invalid for lack of written description support.

468. In addition, in my opinion, a POSA would be left to determine how to move the units display every ejection, while moving the tens display only once every ten ejections and how to fit mechanisms for such movement in a very small space, all with zero guidance from the specification. Given the breadth of Plaintiffs' construction, the nature of inhalers (very small space to insert counter mechanisms), the lack of any direction provided by the specification, the lack of any working examples with the type of multi-part counter display dose counter that Plaintiffs' construction encompasses, and the likely extensive experimentation a POSA would need to engage in to develop a multi-part counter display dose counter, under Plaintiffs' construction, the Asserted Claims of the '808 Patent are also invalid for lack of enablement.

XVIII. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

469. I understand that it is Teva's burden to assert any secondary considerations of non-obviousness regarding the patents in this matter and, to the extent Teva brings forward such assertions, I expect to respond to them.

470. I know of no secondary considerations that would tend to suggest that any of the asserted claims in this matter are not obvious over the prior art. The "primary" considerations of obviousness discussed above, including the scope and content of the prior art discloses all of the claimed limitations, the strong motivation to combine the prior art in a predictable way to create the claimed inventions, the lack of differences between the prior art and the claimed inventions, the lack differences between the prior art and the claimed inventions, and the level of ordinary skill in the art would overcome any secondary considerations of non-obviousness. Thus, it is my view that even if any such secondary considerations exist and are proven by Teva, those considerations do not overcome the abundance of prior art which demonstrates that the subject matter the asserted patents would have been obvious to a POSA at the time of the alleged inventions.

471. Based on my review of Teva's Supplemental Response to Interrogatory No. 4 and Response to Invalidity Contentions, it appears that Teva may attempt to argue that the following secondary considerations are applicable: long-felt, unmet need in the industry, praise by others, copying by others, failure of others, and industry acceptance. I have considered these arguments, and they do not change my opinions that the Asserted Claims would have been obvious. I respond to Teva's conclusory statements here, but I reserve the right to rebut any more formal arguments regarding secondary considerations presented by Teva or its experts during this case.

472. Teva claims that there was a long-felt, unmet need for dose counters "with sufficient functionality, accuracy (including, with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on

device performance, and human facts (including aesthetics, ergonomics, and other human factors")." I disagree. As of the earliest priority date of the Asserted Patents, May 2010, dose counters existed that are still incorporated in products marketed today. *See, e.g.*, Dulera (incorporating the dose counter described in the '406 Publication). Numerous products, including Advair, Xopenix, Ventolin, and Flovent incorporated inhalers before May 2010, and still use the same dose counters. Advair 2008 Label, Xopenix HFA Label, Ventolin HFA Label. Notably, the 2003 FDA Guidance, Ogren[5], Fink[6], Broeders[7], and Sander[8], that Teva relies on to establish a "long-felt, unmet need" pre-date the general incorporation of dose counters (2008) in inhalers in the United States by several years. By May 2010, dose counters were commonly incorporated in inhalers. In addition, today, the use of dose counters in inhalers is ubiquitous, yet the dose counter claimed in the Asserted Patents is found in just two products (one of which has been discontinued).

473. Teva also claims that others have tried and failed to develop dose counters with the desirable features described above. However, as discussed above, numerous dose counters were marketed prior to May 2009 and continue to be marketed today, including the 3M/Kindeva dose counter described in the '406 Publication, and incorporated into Dulera, the Cipla ANDA Product,

---

[5] Ogren, et al, How Patients Determine When to Replace Their Metered-Dose Inhalers, Annals of Allergy, Asthma, & Immunology, Vol. 75, December (Part 1), 1995:485-489.

[6] Fink & Rubin, Problems with Inhaler Use: A Call for Improved Clinician and Patient Education, 50 Respiratory Care 1360 (2005)

[7] Broeders, et al, The Admit Series – Issues in Inhalation Therapy. 2) Improving Technique and Clinical Effectiveness, Primary Care Respiratory Journal, 2009, 18(2): 76-82. Although published in 2009, it was submitted in 2008, around the time the FDA began approving dose counters and therefore is incorrect in its statement that MDI inhalers do not include dose counters, at least after 2008.

[8] Sander, et al, Dose Counting and the Use of Pressurized Metered Dose-Inhalers: Running on Empty, Am. Allergy Asthma Immunol. 2006, 97:34-38.

and the Aurobindo ANDA Product. Although Teva identifies companies that it claims tried and failed to develop dose counters, it does not cite any evidence to support its contentions.

474. Next Teva cites "industry acceptance" as evidence of non-obviousness. It is my understanding that this is not evidence of non-obviousness. The FDA has approved numerous dose counters. Its approval has nothing to do with the novelty of a device.

475. Teva also cites praise for the claimed invention. However, the two cited articles do not support this premise. First, Chipps 2017 was a study ***funded by Plaintiffs***. In addition, the conclusion was only that ProAir HFA with a dose counter had "lower healthcare resource use including all-cause and respiratory-related and inpatient and ED visits, higher refill rates, and fewer exacerbations." This "praise" is attributable to the presence of a dose counter, not the particularly claimed dose counters. Given 2012 was similarly a study ***funded by Plaintiffs***. In addition, this study merely concluded that "ProAir HFA MDI with the new integrated dose counter functioned reliably and accurately in the clinical setting." This conclusion is a far cry from praise. Moreover, the only inhaler used in the study was the ProAir HFA MDI, so this study could not even conclude that the dose counter used therein was more reliable or accurate than any other dose counter on the market.

476. Finally, Teva alleges that alleged copying by Defendants evidences secondary considerations. First, Teva claims that Defendants copied Qvar, but it is my understanding that copying of the Asserted Claims is the more relevant inquiry. I understand that Defendants use a dose counter disclosed in the '406 Publication, which predates the Asserted Patents. I have also observed that the inhaler bodies are very different. In my opinion, Defendants did not copy the Asserted Claims or the inhaler and dose counter from Qvar.

477. I understand that in order for a secondary consideration to receive substantial weight, the evidence of secondary considerations must have a nexus to the claims. Put differently, I am informed that the secondary consideration evidence must have a sufficient connection to the patented claims. Teva has not demonstrated any nexus or connection between any claimed invention and any secondary consideration. Moreover, Teva's claims of secondary considerations are identical even though the claimed inventions are the four Asserted Patents are allegedly different, further showing that Teva has not demonstrated any nexus or connection between any actual Asserted Claim of an Asserted Patent and alleged secondary consideration.

478. Therefore, I am not aware of any alleged secondary considerations that would change my opinion that the Asserted Claims would have been obvious in view of the prior art discussed herein.

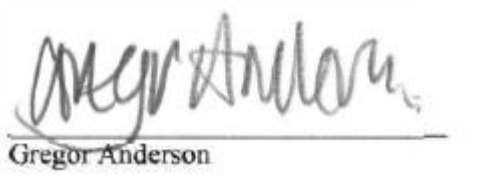
XIX. REVISION OR SUPPLEMENTATION

479. I reserve the right to modify and supplement this report based on information that may subsequently become available in this matter, and to respond to issues yet to be raised in the litigation. I reserve the right to change or formulate new opinions if there is a material change in the law concerning patent infringement between now and trial.

XX. DEMONSTRATIVE EXHIBITS

480. If called to testify at trial, I may prepare demonstrative exhibits, such as charts and graphs, to further explain my opinions.

Dated: 4/29/2022



Gregor Anderson

EXHIBIT A

GREGOR JM ANDERSON: Hitchin, Hertfordshire, UK. Email: gregor@pharmacentricsolutions.com

Mobile: + 44 (0)7789480624 References Available

PERSONAL SUMMARY

Creative senior level technical leader with a proven track record in delivering large scale pharmaceutical device and packaging platforms complimented by both Consumer Healthcare and Medical Device development experience. I implement device and packaging programmes from medicine vision to marketplace and lead multi million-dollar NPI projects and create global device and packaging strategies. Device specialities include: respiratory, injector and connected devices.
Through 2016/17 I was Industry Lead for the Medicines Manufacturing Industry Partnership and GSK packaging project head (https://www.bioindustry.org/policy/manufacturing/mmip.html). As part of my MMIP role I authored the Technology and Innovation Roadmap for UK Pharma that was published in Aug 2107 (http://www.abpi.org.uk/about-us/resources/publications-library/manufacturing-vision-for-uk-pharma-future-proofing-the-uk-through-an-aligned-technology-and-innovation-road-map/). The roadmap continues to be used as the core strategy for ongoing manufacturing investment for UK Pharma/government.

Areas of Expertise, Key Skills and Competencies

Product and process development – NPI and Product Lifecycle
Project management –Complex line/matrix projects
Leadership – of expert teams with global reach
Risk / issue management- industry standards / due diligence
Strategic -Patient focussed and commercially aligned
Performance improvement – Products and people
Device/supplier selection – Robust decision making
Design for manufacture – From concept to production

- Innovator -named on 40+ patents and award winner for both drug device & packaging solutions
- Knowledge of global regulatory, quality and supply chain requirements within Pharma
- Scientific and engineering of various dose forms including processes and controls
- Strong commercial acumen - commercial strategies and brand development
- In-depth knowledge of the drug development process including more recent combination legislation
- Highly effective influencing skills at a Senior Exec / Opinion Leader levels
- Preparing relevant sections of FDA/Regulatory Submissions / Design History Files
- Collaborator with substantial interaction with specialist manufactures / assemblers
- Ability and experience working and communication across a wide range of cultures/countries
- Undertaking Due Diligence and preparing comprehensive business cases
- Organisational development including team creation, motivation, mentoring, management

SUMMARY OF JOB HISTORY

Managing Director – Pharmacentric Solutions **Oct 2017 -**

Consultancy specialising in packaging and device development & strategy from initial concept through to production.

Global Device & Pack Subject Matter Expert (SME), Respiratory Centre of Excellence (GMS) **April 2012 – Oct 2017**

Responsible SME for device innovation and product lifecycle strategies to enable and enhance respiratory (and non-respiratory) platforms, supporting global GSK manufacturing sites. Accountable for managing device and equipment interface collaborating with internal and external expertise to deliver solutions. Projects include:

- Accountable lead for the development of novel pack for Ellipta Dry Powder. It has subsequently won 2 Design Awards in 2015. Design engineer on original Imigran Auto-injector, Diskus, MDI Dose Counter, and Ellipta platform.
- Support Brand Reviews of our heritage GSK blockbuster brand lifecycle strategies including Due Diligences.
- Led Pack Development for the GSK Africa 2020 project. Using Voice of the Customer studies to design/specify 'Africa-Pack' for all packaging platforms and prepared GSK Packaging Strategy for Africa.
- Programme lead to identify a GSK BioPharm Safety Syringe standard platform (managing a team including commercial/site/procurement). Led through GSK governance to full approval (including injector training strategy).
- Developed and launched 3 Training devices for GSK Dry Powder Platforms. Partnered with UK respiratory sales team to introduce trainers into national scheme. Supported Biopharm commercial to design & deliver training strategies.
- Undertook business analysis with EMAP commercial teams in 4 regions to identify opportunities for Respiratory platforms. Subsequently I led the development launch of 3 respiratory devices to enable patient access.

Global Technical Head, Packaging Centre of Excellence (CoE), Global Manufacturing Services (GMS) April 2009 –April 2012

- Built and led a multi skilled technical CoE packaging team (7 'expert' staff) in early 2009 and delivered packaging equipment and materials benefits of £11.9M in 2009 and £7.4M in 2010. 2011 benefits of £13.25M delivered. Focus was to improve efficiencies and reduce waste whilst identifying and implementing innovative packaging solutions.
- Delivery of the Global Distribution Project to deliver a reduction of over 5000 pallets through re-engineering pallet cube configurations across 15 European sites. Cost and CO2 savings won this project a GSK Presidents Award.
- Responsible for the delivery of a pandemic device packaging/artwork solution with efficiencies that saved £2.4M on equipment. Pack/device simplification reduced Cost of Goods by 34%.
- Created an alliance with Asian site to enable their 2015 Site Master Plan to save over £2.6M.
- Created and launched the GSK Green Packaging Guide, with inclusion of a 2020 packaging target into the GSK CSR.

Device Design Director, GSK R&D April 2007 –April 2009

- Accountable for leading a team of 26 engineers/scientists to develop a novel metered dose inhaler (MDI). Project was completed and patented technical learning transferred to our dry powder devices.
- Developed and tested GSK Child Resistant /Senior Friendly pack formats to meet updated regulatory requirements.

Design Manager, GSK R&D Nov 2000 -April 2007

- Reorganised and led a multi-skilled team of design/process engineers, analysts and formulators on a multimillion-pound device development program for a next generation dry powder inhaler (headcount of 35 staff). Responsible for all aspects of project delivery**.** The project led to various spin offs to include the latest Ellipta dry powder device.
- Initiated and managed Consumer Healthcare/OTC design resource that spun out into a separate design team within CH. Developed devices and packaging for smoking cessation/oral healthcare/nutritionals; some included electronics.

Design Team Leader, GlaxoWellcome R&D Nov 1998 - Nov 2000

- Led GSK's first 'Voice of the Customer' project. This was a global market research study to identify and measure present and future customer needs around the use of respiratory devices. Patents and refined device designs were driven from the study results (including the GSK MDI Dose counter). VoC Methodology is still used across GSK projects and incorporated into each 'Medicine Vision' and has evolved into what is now defined as Human Factors.

Principal Device Design Engineer, GlaxoWellcome R&D April 1995 – Nov 1998

- Design lead with a Technology Partner to develop a 'next generation' Liquid Inhaler. Responsible for designing and manufacturing prototypes for clinical trials and concept designs. Managed a team of engineers and I was accountable for 'design for manufacture' /quality/risk assessments. Program stopped due to formulation limitations
- Concept engineering on novel dose counter for MDI-World's first dose counter to be approved by FDA.

Senior Device Design Engineer, Glaxo May 1989 – April 1995

- Designer on Diskus Inhaler Team (won over 5 design awards -inc Queens Award- and generated revenue of £5B pa).
- Design lead on Imigran injector (collaborated with supplier to develop & launch). Created a launch strategy with commercial that included compliance packaging solutions for solid dose Imigran and a single dose nasal version.

Senior Design Engineer, Portex, (SIMS) May 1988 – May 1989

- Developed/launched patented adjustable Tracheotomy Tube & Wound Drainage device.

Design Engineer, Portex , Smiths Industries Medical Systems (SIMS) Oct 1986 –Jan 1988

- Developed/launched range of paediatric products working in partnership with Great Ormond St.

EDUCATION

1991 – 1993 **MSc Polymer Science and Engineering** – University of North London-Masters Degree with Distinction

1985 – 1986 **Postgraduate Diploma in Marketing** – Heriot-Watt University, Edinburgh

1981 – 1985 **BSc (CNAA) Industrial Design & Technology** - Napier University, Edinburgh. Awarded Degree with Commendation and Betts Brown Award for best Final Year Project – Inset 500 Portable Infusion Set

PATENTS AND APPLICATIONS

Patent/Application No	Title
WO2004026378A2	Method for Loading a Medicament Dispenser with a Medicament Carrier
WO2005115889A2	A Dispenser

WO03023663A2	Permission-Based Marketing System
WO0228739A2	Container with Removable Protective Cover
WO03090825A1	Medicament Dispenser
US2012240742A1	Novel Device
USD417148S	Blister for a Blister Pack
USD415416S	Blister for a Blister Pack
CZ477699A3	Device for Holding Blister Package and Blister Package Per Se
WO0018456A1	Inhalation Device
US2012006322A1	Drug Dispenser
WO0018458A1	Inhalation Device
WO9913930A1	Intranasal Administration Device
WO0053247A1	Medicament Delivery System
WO0128616A1	Medicament Pack
WO0045879A1	Inhalation Device
WO0147590A1	Dispenser with Biased Cover
US2006069345A1	Casing
MXPA01009570A	Valve
US6338408B1	Device for Holding Blister Pack
USD411445S	Holder for Blister Packs
USD414106S	Holder for Blister Packs
USD337052S	Tablet Case
USD336611S	Tablet Case
MXPA03003853A	Medicament Dispenser
USD437931S	Inhalation Device
USD391369S	Inhalation Device
USD344183S	Key Fob
AU2779989A	Tracheal Tube Fittings and Assemblies
WO0110741A1	Valve with a Two-Component Seal
WO2005067813A1	Foldable Electrical Toothbrush
WO03074189A1	A Fluid Dispensing Device
US2005103330A1	Process of Manufacturing Drug Delivery Sprayheads
WO2004009470A2	Medicament Dispenser
AU4778990A	Adjustable Fitments for Medical Tubes
USD446718S	Container for pharmaceutical tablets
USD445496S	Inhalation Device
WO2004108197A1	Nozzle
USD514222S	Inhaler
USD754533S	Tray Package for an Inhalation Device
ZA200106111B	Metering Valve
ES2727926T3	Distribuidor de Fármacos
USD538649S	Dispensing Attachment for Dispensing Unit Products, for Instance Pills
WO0141849A2	Medicament Dispenser
WO0124690A2	Medicament Delivery System
WO2007068900A2	Medicament Dispenser
WO2008023018A1	Actuator for an Inhaler
WO2008023013A1	Actuator for an Inhaler
WO2008023015A1	Actuator for an Inhaler
GB2583749A	A Collection Container
AU5053100A	Inhalation Device
ZA200405701B	Medicament Dispenser
WO2019008336A1	Inhaler
WO2005005280A1	A Hand-Held Dispenser for Dispensing Unit Products
WO0198175A1	Method and Package for Storing a Pressurized Container Containing a Drug
WO2008110584A2	Drug Dispenser
WO2005004787A1	A Dispenser
WO2005004785A2	A Dispenser
WO2005004786A1	A Dispenser
USD662199S	Mouthpiece
US2009078252A1	Fault Indicator
USD653326S	Inhaler
ZA200607135B	A Dispensing Device

PUBLICATIONS

Manufacturing Vision for UK Pharma (https://www.abpi.org.uk/media/1344/manufacturing_vision_for_uk_pharma.pdf)

Sustainability in Inhaled Drug Delivery. Pharmaceutical Medicine ISSN 1178-2595 Volume 34 Number 3 Pharm Med (2020) 34:191-199 DOI 10.1007/s40290-020-00339-8

Sustainable Inhaler Challenge – Learning from Non-Pharma Industry Trends and Drivers and applying these opportunities to future inhaler platforms - RDD 2020

Shaping the future: Using Voice of the Customer methodology to develop inhaler design. RDD (Respiratory Drug Delivery) 2001

Downtime and extra curriculum projects

I enjoy motorcycling/cycling & snowboarding. I am a School Governor (Vice Chair) at a large secondary -I strongly believe that you put something back into your community-. I love my 1968 Triumph Vitesse that reminds me how to service a car (after fully rebuilding it). I also am on the Board of The Packaging Society where I represent the Pharmaceutical Industry.

EXHIBIT B

EXHIBIT B

MATERIALS CONSIDERED BY GREGOR ANDERSON

Description	Bates No.
U.S. Patent No. 9,463,289	
U.S. Patent No. 9,808,587	
U.S. Patent No. 10,086,156	
U.S. Patent No. 10,561,808	
Plaintiffs' Infringement Contentions to Cipla	
Plaintiffs' Infringement Contentions to Aurobindo	
Plaintiffs' Response to Cipla's Invalidity Contentions	
Teva's Supplemental Response to Interrogatory No. 4	
Cipla's Invalidity Contentions	
Aurobindo's Invalidity Contentions	
Sample of Cipla's ANDA Product	
Sample of ProAir Inhaler	
Sample of Qvar Inhaler	
'289 Patent File History, March 7, 2016 Office Action Response	
'289 Patent Prosecution History, May 20, 2016 Notice of Allowance	
'587 Patent Prosecution History, February 7, 2017 Office Action	
'156 Patent Prosecution History, May 31, 2018 Notice of Allowance	
'808 Prosecution History, Dec. 16, 2016 Office Action	
'808 Prosecution History, March 15, 2017 Response to Office Action	
'808 Prosecution History, April 11, 2017 Office Action	
'808 Prosecution History, July 6, 2017 Office Action Response	

'808 Prosecution History, July 7, 2019 Office Action	
'808 Prosecution History, Sept. 9, 2019 PTO Board Decision	
Cipla dose counter schematic drawing	CIPLA-BDI_0156579
Aurobindo dose counter schematic drawing	AURO_BECL00005977
Advair 2008 Label	CIPLA-BDI_0183908-4002
Xopenex HFA Label	CIPLA-BDI_0184721-41
Ventolin HFA Label	CIPLA-BDI_0184396-420
International Patent Publication No. WO 2007/124406	CIPLA-BDI_0184003-99
International Patent Publication No. WO 2008/119552	CIPLA-BDI_0184693-720
U.S. Patent Application Publication No. US 2005/0087191	CIPLA-BDI_0184214-290
International Patent Publication No. WO 2007/103712	CIPLA-BDI_0184646-692
International Patent Publication No. WO 2003/101514	CIPLA-BDI_0184421-469
U.S. Patent No. 6,446,627	CIPLA-BDI_0184357-371
U.S. Patent No. 4,817,822	CIPLA-BDI_0184347-356
U.S. Patent No. 7,407,066	CIPLA-BDI_0184372-378
European Patent Publication No. EP 1,369,139	CIPLA-BDI_0184888-912
United Kingdom Patent Publication No. GB 2,320,489	CIPLA-BDI_0184913-943
U.S. Patent Application Publication No. US 2005/0209558	CIPLA-BDI_0184988-5008
United Kingdom Patent No. GB 994,755	CIPLA-BDI_0184742-746
European Patent Publication No. EP 1,321,159	CIPLA-BDI_0184759-779
U.S. Patent Application Publication No. US 2006/0289008	CIPLA-BDI_0184315-328
International Patent Publication No. WO 2006/126965	CIPLA-BDI_0184554-593
U.S. Patent Application Publication No. US 2007/0277817	CIPLA-BDI_0184329-337
International Patent Publication No. WO 2005/113044	CIPLA-BDI_0184507-553
U.S. Patent Application Publication No. 2002/0047021	CIPLA-BDI_0184944-973
Metered-Dose Inhalers: Actuators Old and New, Lewis, Expert Opn. Drug. Deliv 4(3):235-245 (2007)	CIPLA-BDI_0184747-758

U.S. Patent Application Publication No. US 2006/0107949	CIPLA-BDI_0184291-314
FDA Guidance for Industry, Integrations of Dose-Counting Mechanisms into MDI Drug Products, US Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Clinical Medical, March 2003	TEVAQVAR-00032573-579
U.S. Patent Application Publication No. US 2007/0062518	CIPLA-BDI_0185009-061
U.S. Patent Application Publication No. US 2007/0210102	CIPLA-BDI_0185277-291
U.S. Patent Application Publication No. US 2002/0078950	CIPLA-BDI_0184200-213
U.S. Design Patent No. D416,998	CIPLA-BDI_0184391-395
U.S. Patent No. 8,584,668	CIPLA-BDI_018379-390
International Patent Publication No. WO 2004/060260	CIPLA-BDI_0184470-506
Ogren, et al, *How Patients Determine When to Replace Their Metered-Dose Inhalers*, Anals of Allergy, Asthma, & Immunology, Vol. 75, December (Part 1), 1995:485-489	TEVADOC_00000011-15
Fink & Rubin, *Problems with Inhaler Use: A Call for Improved Clinician and Patient Education*, 50 Respiratory Care 1360 (2005)	CIPLA-BDI_0184184-199
Broeders, et al, *The Admit Series – Issues in Inhalation Therapy. 2) Improving Technique and Clinical Effectiveness*, Primary Care Respiratory Journal, 2009, 18(2): 76-82	TEVADOC_00000001-7
Sander, et al, *Dose Counting and the Use of Pressurized Metered Dose-Inhalers: Running on Empty*, Am. Allergy Asthma Immunol. 2006, 97:34-38	TEVADOC_00000046-50
Chipps, et al, *Impact of Integrated Dose Counter on Healthcare Utilization and Disease Control in Medicare Patients with Asthma and/or Chromic Obstructive Pulmonary Disease using Albuterol Sulfate Inhalation Aerosol (proair Hfa)*, Am J Respir Crit Care Med, 2017; 195:A2983	TEVADOC_00000008-9
Given, et al, *Open Label Assessment of Proair® Hfa Metered Dose Inhaler with a New Integrated Dose Counter*, Am J Respir Crit Care med 185; 2012:A5621	TEVADOC_00000010